

**THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Appellant(s): Sherwin Shang et al.
Appl. No.: 09/917,136
Conf. No.: 3282
Filed: July 27, 2001
Title: AUTOCLAVABLE, NON-ADHERENT, HEAT SEALABLE POLYMER
FILMS FOR FABRICATING MONOLAYER AND MULTIPLE LAYERED
FILMS AND CONTAINERS
Art Unit: 1711
Examiner: Jeffrey C. Mullis
Docket No.: CPDI-5596A (112713-913)

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' APPEAL BRIEF

Sir:

Appellants submit this Appeal Brief in support of the Notice of Appeal filed on April 23, 2007. This Appeal is taken from the Final Rejection in the Office Action dated January 22, 2007.

I. REAL PARTY IN INTEREST

The real party in interest for the above-identified patent application on Appeal is Baxter International Inc. by virtue of an Assignment dated January 28, 2002 and recorded at reel 012394, frame 0146 in the United States Patent and Trademark Office.

II. RELATED APPEALS AND INTERFERENCES

Appellants' legal representative and the Assignee of the above-identified patent application do not know of any prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision with respect to the above-identified Appeal.

III. STATUS OF CLAIMS

Claims 16-19 and 145-161 are pending in this application. Claims 1-15, 20-144 and 162-194 were previously canceled. Claims 16-19 and 145-161 stand rejected. Therefore, Claims 16-19 and 145-161 are being appealed in this Brief. A copy of the appealed claims is included in the Claims Appendix.

IV. STATUS OF AMENDMENTS

A final Office Action was mailed on January 22, 2007. Appellants filed a response to the final Office Action on March 22, 2007 with an amendment to Claim 145 to overcome the 35 U.S.C. §112 rejection. An Advisory Action was mailed on April 12, 2007. In the Advisory Action, the Examiner entered the amendment rendering moot the 35 U.S.C. §112 rejection but maintained the previous anticipation and obviousness rejections. Appellants filed a Notice of Appeal and Pre-Appeal Brief Request for Review on April 23, 2007. A Notice of Panel Decision from the Pre-Appeal Brief Review was mailed on May 2, 2007 that maintained the application under appeal. A copy of the final Office Action, the Advisory Action and the Notice of Panel Decision are attached as Exhibits A, B and C, respectively, in the Evidence Appendix.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A summary of the invention by way of reference to the specification and/or figures for each of the independent claims is provided as follows:

Independent Claim 23 is directed a monolayer film comprising a polymer blend composed solely of a first component and a second component (page 6, line 30 to page 7, line 8; page 8, lines 14-20; Figure 1). The first component is cross-linked and selected from the group consisting of an ethylene containing polymer (page 6, line 30 to page 7, line 8; page 8, lines 1-8; page 8, lines 23-31; page 13, lines 1-20). The first component is present in an amount by weight of the film from about 55% to about 99% (page 6, line 30 to page 7, line 8; page 8, lines 1-8; page 13, lines 24-31; page 14, lines 1-14). The first component has a first melting point temperature determined by DSC (page 6, line 30 to page 7, line 8; page 15, lines 22-29; Figure 7). The second component is selected from the group consisting of propylene containing polymers and methyl pentene containing polymers (page 6, line 30 to page 7, line 8; page 8, lines 9-13; page 9, line 17 to page 10, line 14; page 14, line 15 to page 15, line 5). The second component is present in an amount by weight of the film from about 45% to about 1% (page 6, line 30 to page 7, line 8; page 8, lines 9-13). The second component has a second melting point temperature determined by DSC and is not crosslinked (page 6, line 30 to page 7, line 8; page 14, line 15 to page 15, line 5; page 15, lines 22-29; Figure 7).

Although specification citations are given in accordance with C.F.R. 1.192(c), these reference numerals and citations are merely examples of where support may be found in the specification for the terms used in this section of the Brief. There is no intention to suggest in any way that the terms of the claims are limited to the examples in the specification. As demonstrated by the references numerals and citations below, the claims are fully supported by the specification as required by law. However, it is improper under the law to read limitations from the specification into the claims. Pointing out specification support for the claim terminology as is done here to comply with rule 1.192(c) does not in any way limit the scope of the claims to those examples from which they find support. Nor does this exercise provide a mechanism for circumventing the law precluding reading limitations into the claims from the specification. In short, the references numerals and specification citations are not to be construed as claim limitations or in any way used to limit the scope of the claims.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 16-19 and 145-161 were rejected under 35 U.S.C. §102(e) as anticipated by, or in the alternative, under §103(a) as obvious in view of U.S. Patent No. 6,743,523 to Woo et al. ("*Woo*"). A copy of *Woo* is attached herewith as Exhibit D in the Evidence Appendix.

VII. ARGUMENT

A. LEGAL STANDARDS

1. Anticipation under 35 U.S.C. § 102

“Under 35 U.S.C. § 102, anticipation requires that each and every element of the claimed invention be disclosed in the prior art ...” *Akzo NV v. U.S. International Trade Commission*, 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986). Moreover, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros v. Union Oil of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987).

2. Obviousness under 35 U.S.C. §103

The Federal Circuit has held that the legal determination of an obviousness rejection under 35 U.S.C. § 103 is:

whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made...The foundational facts for the prima facie case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art...Moreover, objective indicia such as commercial success and long felt need are relevant to the determination of obviousness...Thus, each obviousness determination rests on its own facts.

In re Mayne, 41 U.S.P.Q. 2d 1451, 1453 (Fed. Cir. 1997).

In making this determination, the Patent Office has the initial burden of proving a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q. 2d 1955, 1956 (Fed. Cir. 1993). This burden may only be overcome “by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings.” *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q. 2d 1596, 1598 (Fed. Cir. 1988). “If the examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent.” *In re Oetiker*, 24 U.S.P.Q. 2d 1443, 1444 (Fed. Cir. 1992).

Of course, references must be considered as a whole and those portions teaching against or away from the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443 (Fed. Cir. 1986). "A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant." *Monarch Knitting Machinery Corp. v. Fukuhara Industrial Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998), quoting, *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994).

B. THE CLAIMED INVENTION

Independent Claim 23 is directed a monolayer film comprising a polymer blend composed solely of a first component and a second component. The first component is cross-linked and selected from the group consisting of an ethylene containing polymer. The first component is present in an amount by weight of the film from about 55% to about 99%. The first component has a first melting point temperature determined by DSC. The second component is selected from the group consisting of propylene containing polymers and methyl pentene containing polymers. The second component is present in an amount by weight of the film from about 45% to about 1%. The second component has a second melting point temperature determined by DSC and is not crosslinked.

C. THE REJECTIONS OF CLAIMS 16-19 AND 145-161 UNDER 35 U.S.C. §102(E) OR, IN THE ALTERNATIVE, 35 U.S.C. §103(A) SHOULD BE REVERSED BECAUSE WOO IS DEFICIENT WITH RESPECT TO THE CLAIMED INVENTION

1. Woo is not proper prior art

Appellants respectfully submit that *Woo* is not a proper prior art reference because the content of *Woo* relied on for the anticipation and obviousness rejections fails to pre-date the earliest priority date of the present application. The present application is a CIP application and claims priority to U.S. Patent Application Serial No. 09/526,357 filed on March 16, 2000, now

U.S. Patent No. 6,969,483 (the "*Parent*" attached herein as Exhibit E). As a result, the present application has the benefit of a filing date of March 16, 2000 for all that is disclosed and supported in the *Parent*. *Woo* has a filing date of March 16, 2000. As the *Parent* and *Woo* were filed on the same day, *Woo* does not have an earlier filing date with respect to the *Parent*.

In addition, the Examiner's entire support for the alleged anticipation and obviousness rejections in view of *Woo* come from the data shown in the Table found at columns 9-12 of *Woo* (the "*Table of Woo*"). See, Office Action dated August 22, 2006 (attached as Exhibit F) at pages 3 and 5. However, the Table of Woo is identical to Table 2 found on page 21 of the present application. Moreover, Table 2 of the present application is identical to the Table found at columns 11-12 of the *Parent*, and the currently pending application has the priority date of the Parent with respect to the information found in the Table. Thus, the *Table of Woo* that the Examiner's anticipation and obviousness rejections are premised on for showing allegedly showing inherent disclosure of Appellants' claims is also supported in the *Parent*. Accordingly, the *Table of Woo* does not pre-date the priority date of the present application. Simply stated, the *Table of Woo* is disclosed in the *Parent* and the present application and cannot be used as prior art with respect to the present claims.

As *Woo* is not prior art, *Woo* cannot not anticipate or render obvious the present claims. Appellants respectfully request that *Woo* to be removed as a reference.

2. The present claims are fully supported by the *Parent*

The Examiner states that "[i]n order for the present case to possess the filing date of the parent case the full breadth of the instant claims has to be supported by the parent case." See, Advisory Action dated April 12, 2007. The Examiner further states that "While it appears that Appellant's examples disclose compositions in which the second component is not crosslinked, a single example cannot be said to provide support for a claim reciting components which may or may not be present as well as ranges of concentrations." *Id.* Appellants respectfully submit that the Examiner's characterization of the present claims is incorrect and does not accurately present the proper test for establishing an earlier priority date under the patent law.

To be entitled to the filing date of the *Parent*, each element of independent Claim 145, for example, must be expressly, implicitly, or inherently supported by the *Parent*. MPEP § 2163(b).

The test for determining whether the present claims are supported by the *Parent* is whether the *Parent* reasonably conveys to the skilled artisan that the Appellants had possession of the claimed subject matter at the filing date of the *Parent*. *Eiselstein v. Frank*, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995).

One of ordinary skill in the art would recognize that the Appellants had possession of the presently claimed subject matter at the filing date of the *Parent*. For example, contrary to the Examiner's assertions, Table 2 at page 21 of the present specification (supported by the *Parent* as discussed above), provides numerous examples of polymeric films containing a cross-linked ethylene component and a non-crosslinked propylene component. The Examiner has admitted that Table 2 of the *Parent* application does indeed support the present claims. See, Advisory Action dated April 12, 2007 ("While it appears that Appellant's examples disclose compositions in which the second component is not crosslinked..."); See, also, Office Action dated August 22, 2006 at page 3 whereby the Examiner asserts an anticipation rejection based on the *Table of Woo* (which is disclosed in the *Parent* as discussed above).

In addition, the *Parent* along with the corresponding present application provide numerous examples of what the first component and the second component of the claimed polymer blend can comprise. For example, as with the present application, the *Parent* teaches that the first component can be (1) ethylene and α -olefin interpolymers having a density of less than about 0.915 g/cc, (2) ethylene and lower alkyl acrylate interpolymers and (3) ethylene and lower alkyl substituted alkyl acrylate interpolymers. See, the *Parent*, column 6, lines 1-24. The *Parent* also teaches that the second component can be propylene containing polymers and polymethylpentene containing polymers. See, the *Parent*, column 6, lines 1-24. Further, the *Parent* teaches that the first component is present in an amount from about 99% to about 55% and the second component is present in an amount by weight of the blend from about 45% to about 1%. See, the *Parent*, column 6, lines 2-23. Consequently, the *Parent* at least discloses and provides numerous examples for the elements of independent Claim 145. If independent Claim 145 is novel and non-obvious, then the claims that depend from Claim 145 are novel and non-obvious as well.

Appellants also respectfully submit that the Examiner's assertion stating that a single example cannot support a claim is misplaced. Disclosure of a representative compound may provide implicit description upon which to base generic claim language. *In re Smith*, 173 USPQ

679, 683 (CCPA 1972). Moreover, the specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). Nevertheless, Table 2 of the present application provides, not one, but numerous examples of polymeric films containing a cross-linked ethylene component and a non-crosslinked propylene component.

The Examiner has admitted that Table 2 supports the present claims. Table 2 is supported by the *Parent*. All the elements of independent Claim 145 are disclosed in the *Parent*. Thus, one of ordinary skill in the art would recognize that the Appellants had possession of the presently claimed subject matter at the time the *Parent* was filed. The present claims are therefore supported by the *Parent* and not anticipated or rendered obvious by *Woo*.

For at least the reasons discussed above, *Woo* is deficient with respect to the present claims. Accordingly, Appellants respectfully submit that Claim 145 and Claims 16-19 and 146-161 that depend from Claim 145 are novel, nonobvious and distinguishable from the cited reference and are in condition for allowance.

VIII. CONCLUSION

Appellants respectfully submit that the Examiner has failed to establish anticipation and a *prima facie* case of obviousness under 35 U.S.C. §103 with respect to the rejections of Claims 16-19 and 145-161. Accordingly, Appellants respectfully submit that the anticipation and obviousness rejections are erroneous in law and in fact and should therefore be reversed by this Board.

A check in the amount of \$500 is submitted herewith to cover the cost of the Appeal Brief. The Director is authorized to charge any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112713-913 on the account statement.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY 

Robert M. Barrett
Reg. No. 30,142
Customer No. 29200

Dated: June 18, 2007

CLAIMS APPENDIX
PENDING CLAIMS ON APPEAL OF
U.S. PATENT APPLICATION SERIAL NO. 09/917,136

16. The film of claim 145, wherein the methyl-pentene-containing polymer is selected from the group consisting of: homopolymers of 4-methylpentene-1, and copolymers of 4-methylpentene-1.

17. The film of claim 145, wherein the first component is present in an amount by weight of from about 55% to about 90%.

18. The film of claim 145, wherein the first component is present in an amount by weight of from about 60% to about 80%.

19. The film of claim 145, wherein the first component is present in an amount by weight of from about 65% to about 75%.

145. A monolayer film comprising:

a polymer blend composed solely of a first component and a second component, the first component being cross-linked and selected from the group consisting of an ethylene containing polymer, the first component present in an amount by weight of the film from about 55% to about 99%, the first component having a first melting point temperature determined by DSC;

the second component selected from the group consisting of propylene containing polymers and methyl pentene containing polymers, the second component being present in an amount by weight of the film from about 45% to about 1% the second component having a second melting point temperature determined by DSC, and the second component is not crosslinked.

146. The film of claim 145, wherein the second melting point temperature is higher than the first melting point temperature.

147. The film of claim 145 wherein the film is capable of forming a peel seal to itself when heated to above the first melting point temperature but below the second melting point temperature.

148. The film of claim 147 wherein the film is capable of forming a permanent seal to itself when heated above the second melting point temperature.

149. The film of claim 145 wherein the film is capable of being sterilized by steam at a temperature from about 100°C to about 130°C.

150. The film of claim 146, wherein a peel seal heat sealing window is defined between a range of temperatures existing between the first melting point temperature and the second melting point temperature.

151. The film of claim 150, wherein the peel seal heat sealing window includes at least one temperature point within a range of temperatures suitable for steam sterilization.

152. The film of claim 150, wherein the peel seal heat sealing window includes at least one temperature point within the range of from about 75°C to about 135°C.

153. The film of claim 145 wherein the film is capable of forming a peel seal with itself that is capable of adhesive release.

154. The film of claim 145, wherein the ethylene containing polymer is selected from the group consisting of: ethylene homopolymers, and ethylene copolymers.

155. The film of claim 154, wherein the ethylene copolymer is obtained by reacting ethylene with a comonomer selected from the group consisting of: α -olefins, vinyl esters, vinyl carboxylic acids, alkyl substituted vinyl esters, alkyl substituted vinyl carboxylic acids, acrylic acids, ester derivatives of acrylic acids, alkyl substituted acrylic acids, ester derivatives of alkyl substituted acrylic acids and ion stabilized alkyl substituted acrylic acids.

156. The film of claim 155, wherein the ethylene and α -olefin copolymer has a density of less than about 0.915 g/cc.

157. The film of claim 156, wherein the ethylene copolymer is a single-site catalyzed ethylene copolymer.

158. The film of claim 145, wherein the propylene-containing polymer is selected from the group consisting of propylene homopolymers and propylene copolymers.

159. The film of claim 158, wherein the propylene containing polymer has a modulus of elasticity of less than about 200,000 psi.

160. The film of claim 145, wherein the first component is a blend of ethylene containing polymers.

161. The film of claim 145, wherein the second component is selected from the group consisting of at least one propylene-containing polymer, at least one methyl-pentene-containing polymer, and combinations thereof.

EVIDENCE APPENDIX

EXHIBIT A: Final Office Action dated January 22, 2007

EXHIBIT B: Advisory Action dated April 12, 2007

EXHIBIT C: Notice of Panel Decision from the Pre-Appeal Brief Review dated May 2, 2007

EXHIBIT D: U.S. Patent No. 6,743,523 to Woo et al. ("*Woo*"), cited by the Examiner in the Office Action dated January 22, 2007

EXHIBIT E: U.S. Patent No. 6,969,483 (the "*Parent*")

EXHIBIT F: Non-final Office Action dated August 22, 2006

RELATED PROCEEDINGS APPENDIX

None

EXHIBIT A



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,136	07/27/2001	Sherwin Shang	DI-5396A	3282
29200 7590 01/22/2007 BAXTER HEALTHCARE CORPORATION 1 BAXTER PARKWAY DF2-2E DEERFIELD, IL 60015			EXAMINER MULLIS, JEFFREY C	
			ART UNIT	PAPER NUMBER
			1711 4-22-07	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/22/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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INTELLECTUAL PROPERTY DOCKET

MAR 21 2007

ATTY: EMP-130
DOCKET #: 12113-0913

Office Action Summary**Application No.**

09/017,136

Applicant(s)

SHANG ET AL.

Examiner

Jeffrey C. Mullis

Art Unit

1711

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.139(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-19 and 145-161 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 16-19 and 145-161 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.86(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-852)
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) ☐ Notice of Informal Patent Application
 6) ☐ Other: _____

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Art Unit: 1711

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Claims 16-19 and 145-161 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as filed does not disclose the haze values of "less than or equal to about 17%" and this limitation is therefore new matter. Furthermore the specification as filed does not disclose anything more about how to produce applicants surface haze value than does Woo US 6743523 and as applicants allege Woo has no disclosure whatsoever regarding haze value it follows that it is not present in the instant specification either.

Claims 16-19 and 145-161 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Woo et al. (US 6,743,523).

See the Office action of 8-22-06 at the paragraph bridging pages 2 and 3 et seq.

With re to applicants effective filing date, applicants haze value range does not appear in the parent case although Woo and the instant application share some examples and therefore any characteristic in the examples of instant case would appear to be inherent in Woo also.

Applicant's arguments filed 11-22-06 have been fully considered but they are not persuasive.

The specification as filed does not disclose the haze values of "less than or equal to about 17%" and this limitation is therefore new matter. Furthermore the specification

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as filed does not disclose anything more about how to produce applicants surface haze value than does Woo US 6743523 and as applicants allege Woo has no disclosure whatsoever regarding haze value it follows that it is not present in the instant specification either.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

JCM

1-12-07

Jeffrey Mullis
Primary Examiner
Art Unit 1711



EXHIBIT B

old fee form
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/917,136

07/27/2001

Sherwin Shang

DI-5596A

3282

29200

7590

04/12/2007

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EXAMINER

MULLIS, JEFFREY C

ART UNIT

PAPER NUMBER

1711

MAIL DATE

DELIVERY MODE

04/12/2007

PAPER

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APR 18 2007

ATTY: *BM-B-TSB*DOCKET #: *112713-**0913***RECEIVED**

APR 13 2007

Corporate Patent Administrator

Advisory Action Before the Filing of an Appeal Brief

Application No.

09/917,136

Examiner

Jeffrey C. Mullis

Applicant(s)

SHANG ET AL.

Art Unit

1711

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 March 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). **ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION.** See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(e).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: 16-19 and 145-161.
Claim(s) objected to: _____.
Claim(s) rejected: 16-19 and 145-161.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.

12. ☐ Note the attached Information Disclosure Statement(s). (FTC/SE/06) Paper No(s): _____
13. ☐ Other: _____.

Jeffrey C. Mullis
J Mullis
Art Unit: 1711

Continuation of 11. does NOT place the application in condition for allowance because: In order for the present case to possess the filing date of the parent case the full breadth of the instant claims has to be supported by the parent case. While it appears that applicant's examples disclose compositions in which the second component is not crosslinked, a single example cannot be said to provide support for a claim reciting components which may or may not be present as well as ranges of concentrations. The claims for instance do not exclude crosslinking monomers from the second component (such as diene monomers) and for this reason alone the parent cannot be said to provide support for the full scope of the claims. Furthermore, while the percentages as such in certain of the dependent are supported others are not.

EXHIBIT C



UNITED STATES PATENT AND TRADEMARK OFFICE

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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/917,136

07/27/2001

Sherwin Shang

DI-5596A

3282

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05/02/2007

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EXAMINER

MULLIS, JEFFREY C

ART UNIT

PAPER NUMBER

1711

MAIL DATE

DELIVERY MODE

05/02/2007

PAPER


Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

RECEIVED
BELL, BOYD & LLOYD
INTELLECTUAL PROPERTY DOCKET

MAY 07 2007

ATTY: RMB
DOCKET: 116713-913

Application Number 	Application/Control No. 09/917,136 ***	Applicant(s)/Patent under Reexamination SHANG ET AL. Art Unit 1711	
Document Code - AP.PRE.DEC			

Notice of Panel Decision from Pre-Appeal Brief Review



This is in response to the Pre-Appeal Brief Request for Review filed 4/23/07.

1. ☐ **Improper Request** – The Request is improper and a conference will not be held for the following reason(s):

- ☐ The Notice of Appeal has not been filed concurrent with the Pre-Appeal Brief Request.
- ☐ The request does not include reasons why a review is appropriate.
- ☐ A proposed amendment is included with the Pre-Appeal Brief request.
- ☐ Other:

The time period for filing a response continues to run from the receipt date of the Notice of Appeal or from the mail date of the last Office communication, if no Notice of Appeal has been received.

2. ☒ **Proceed to Board of Patent Appeals and Interferences** – A Pre-Appeal Brief conference has been held. The application remains under appeal because there is at least one actual issue for appeal. Applicant is required to submit an appeal brief in accordance with 37 CFR 41.37. The time period for filing an appeal brief will be reset to be one month from mailing this decision, or the balance of the two-month time period running from the receipt of the notice of appeal, whichever is greater. Further, the time period for filing of the appeal brief is extendible under 37 CFR 1.136 based upon the mail date of this decision or the receipt date of the notice of appeal, as applicable.

☒ The panel has determined the status of the claim(s) is as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 16-19, 145-161.

Claim(s) withdrawn from consideration: _____.

3. ☐ **Allowable application** – A conference has been held. The rejection is withdrawn and a Notice of Allowance will be mailed. Prosecution on the merits remains closed. No further action is required by applicant at this time.

4. ☐ **Reopen Prosecution** – A conference has been held. The rejection is withdrawn and a new Office action will be mailed. No further action is required by applicant at this time.

All participants:

(1) Jeffrey Mullis

(2) Jennifer Michener

(3) James Seidleck

(4) _____

EXHIBIT D



US006743523B1

(12) **United States Patent**
Woo et al.(10) **Patent No.: US 6,743,523 B1**
(45) **Date of Patent: Jun. 1, 2004**(54) **MULTIPLE LAYER FILM OF A NEW NON-PVC MATERIAL**(75) **Inventors:** Lecon Woo, Libertyville, IL (US); Sherwin Shang, Vernon Hills, IL (US); Michael T. K. Ling, Vernon Hills, IL (US); Yuan-pang Samuel Ding, Vernon Hills, IL (US); Tahua Yang, Woodridge, IL (US); Craig Sanford, Wheeling, IL (US)(73) **Assignee:** Baxter International Inc., Deerfield, IL (US)(*) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.(21) **Appl. No.:** 09/526,775(22) **Filed:** Mar. 16, 2000(51) **Int. Cl.** B32B 27/32(52) **U.S. Cl.** 428/516; 428/35.2; 428/35.7; 428/332; 428/475.8; 428/476.1; 428/476.3; 428/476.9; 428/483; 428/517; 428/519; 428/520(58) **Field of Search** 428/35.2, 35.7, 428/332, 475.8, 476.1, 476.3, 476.9, 483, 516, 517, 519, 520(56) **References Cited****U.S. PATENT DOCUMENTS**2,705,223 A 3/1955 Renfrew et al.
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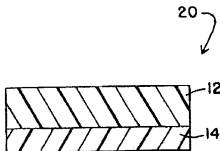
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Primary Examiner—D. S. Nakarani(74) *Attorney, Agent, or Firm*—Mark J. Buonaiuto; Joseph A. Fuchs

(57)

ABSTRACT

The present invention provides a multilayer film. The film has a first layer of a blend of a first component selected from the group of: (1) ethylene and α -olefin copolymers having a density of less than about 0.915 g/cc; (2) ethylene copolymerized with lower alkyl acrylates; (3) ethylene copolymerized with lower alkyl substituted alkyl acrylates and (4) ionomers, the first component being present in an amount from about 99% to about 55% by weight of the blend, a second component in an amount by weight of the blend from about 45% to about 1% and consists of one or more polymers of the group: (1) propylene containing polymers, (2) polybutene polymers, (3) polymethylpentene polymers, (4) cyclic olefin containing polymers and (5) bridged polycyclic hydrocarbon containing polymers; a second layer attached to the first layer; and the film has a modulus of elasticity when measured in accordance with ASTM D882 of less than about 60,000 psi, an internal haze when measured in accordance with ASTM D1003 of less than about 25%, an internal adhesion ranking of greater than about 2, a sample creep at 120° C. under 27 psi loading of less than or equal to 150% for a film having a thickness of from about 5 mils to about 15 mils, and the film can be heat sealed into a container having seals wherein the seals remain intact when the container is autoclaved at 121° C. for one hour.

58 Claims, 2 Drawing Sheets

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FIG. 1



FIG. 2

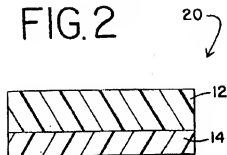
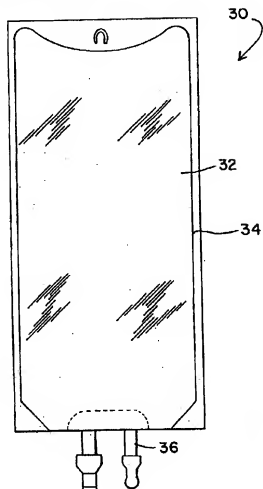
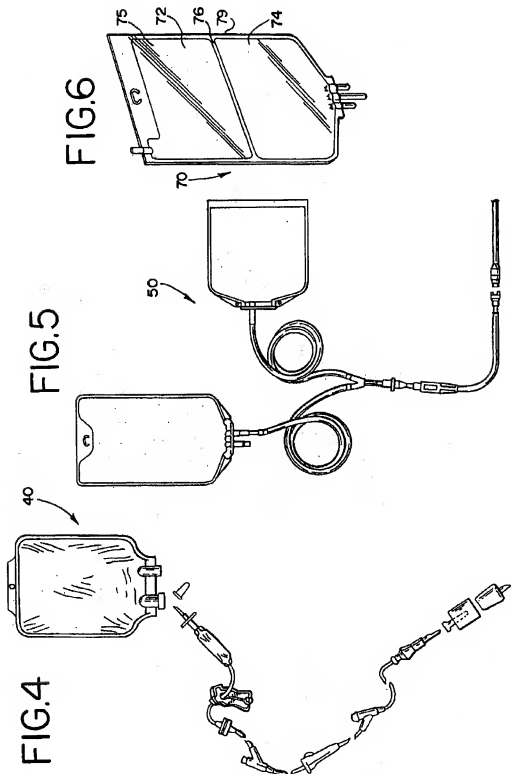


FIG. 3





MULTIPLE LAYER FILM OF A NEW NON-PVC MATERIAL

TECHNICAL FIELD

The present invention relates generally to polymer blends for fabricating films and more particularly films that have low distortion and are non-adherent upon steam sterilization, are heat sealable and are suitable for fabricating into flexible medical containers.

BACKGROUND OF THE INVENTION

In the medical field, where beneficial agents are collected, processed and stored in containers, transported, and ultimately delivered through tubes by infusion to patients to achieve therapeutic effects, materials which are used to fabricate the containers must have a unique combination of properties. For example, visual inspection of solutions for particulate contamination requires an optically transparent container. The material which forms the wall must be sufficiently flexible to infuse a solution by collapsing the container walls, without introducing air into the container. The material must maintain its flexibility and toughness over a wide range of temperatures. The material must maintain its flexibility and toughness at low temperatures because some solutions, for example, certain premixed drug solutions, are stored and transported in containers at temperatures such as -25 to -30° C. to minimize the drug degradation. The material must also be functional and resist distortion at high temperatures to withstand the heat of steam sterilization; a process which most medical fluid containers and nutritional products are subjected to prior to shipment. The sterilization process usually includes exposing the container to steam at temperatures typically 121° C. and at elevated pressures.

For ease of manufacture into useful articles, it is desirable that the material be sealable using heat sealing techniques. The material therefore must maintain sufficient thermoplastic properties to melt upon heating.

A further requirement is to minimize the environmental impact upon the disposal of the article fabricated from the material after its intended use. For those articles that are disposed of in landfills, it is desirable to minimize or avoid the incorporation of low molecular weight leachable components to construct the article. Further benefits are realized by using a material that allows thermal reprocessing of scrap material produced during manufacturing.

For those containers which are disposed of through incineration to minimize biological hazards, it is desirable to use a material that minimizes or eliminates the formation of environmentally undesirable and corrosive inorganic acids.

It is also desirable that the material be free from or have a low content of low molecular weight additives such as plasticizers, stabilizers and the like which could be released into the medications or biological fluids.

Due to its ability to meet a wide variety of functional requirements, flexible polyvinyl chloride (PVC) has frequently been the material of choice for medical bag applications. PVC also offers the distinct advantage of being one of the most cost-effective materials for constructing devices that meet the above requirements. However, PVC has a number of disadvantages in the marketplace. These disadvantages include incompatibility of PVC compounds with certain drugs, concerns regarding chlorine content and its effects on the environment and a growing negative market perception of PVC in general. Thus, many materials have

been devised to replace PVC. However, most alternate materials are too expensive to implement and still do not meet all of the above requirements.

Polyolefins and polyolefin alloys have been developed which meet many of the requirements of medical containers and tubing, without the disadvantages associated with PVC. Polyolefins typically are compatible with medical applications because they have relatively low extractability to fluids. Most polyolefins are environmentally sound as they do not generate harmful degradants upon incineration, and are suitable for thermoplastic recycling. Many polyolefins are cost effective materials that may provide an economic alternative to PVC. However, there are many hurdles to overcome to replace all the favorable attributes of PVC with a polyolefin.

For example, problems have been encountered in using certain polyolefins to fabricate medical tubing. Such tubing has been found to have poor surface characteristics so that it is readily susceptible to cutting, shredding or scoring when clamping the tubing using a slide clamp. Also, certain polyolefins that have favorable modulus attributes, such as ultra-low density polyethylenes, have melting point temperatures below that reached during an autoclave process.

It is well known that cross linking by chemical agents or by high energy ionizing radiation increases heat resistance of the polymer matrix. The chemical cross-links are covalent bonds across separate polymer chains that greatly retard the tendency to deform and flow at high temperatures—even above the melting point of the polymer. For example, U.S. Pat. No. 4,465,487 assigned to Terumo discloses fabricating steam autoclavable medical containers by irradiating ethylene vinyl acetate copolymers with high energy (2 Mev) electron beams at doses between 50 kGy and 100 kGy to achieve gel contents of between 50% and 85%. The '487 Patent discloses that if the EVA sidewalls of the container are irradiated to achieve a gel content of about 50% or higher before being sealed together they are easily peeled apart. (Col. 4, lines 20-30). Accordingly, the '487 Patent discloses irradiating the sidewalls of the container after sealing the container into a pouch leaving only a port area unsealed.

Similarly, U.S. Pat. No. 4,453,940 discloses fabricating medical containers from EVA and other materials. The '940 Patent also discloses the step of increasing the autoclave resistance of EVA by cross-linking the material with high energy electron beam. The '940 Patent warns that if the cross-linking exceeds 50% the use of heat sealing becomes impossible. (Col. 4, lines 27-35).

U.S. Pat. No. 4,401,536 discloses crosslinking semi-rigid containers composed of blends of polypropylene and EVA or EEA. This patent does not disclose the use of ethylene alpha olefins with polypropylene. It also discloses that irradiation before forming results in articles with poor heat sealability (Col.4, lines 25-28).

U.S. Pat. Nos. 4,892,604 and 5,066,290 both assigned to the present assignee, disclose a medical container with a coextruded high density polyethylene skin layer and a core layer of an ethylene vinyl acetate copolymer having about 18% vinyl acetate content. After the container is fabricated by conventional radio frequency heat seal, the assembly is subjected to ionizing radiation of about 100 kGy from a high energy electron beam accelerator of about 5 Mev. The high density polyethylene layer acts as a moisture and gas transmission barrier to maintain the sterile fluid content at a relatively constant concentration as required by various pharmacopoeia of the world. However, several serious deficiencies were apparent in this material construction: 1) to

fabricate a container from this material construction the container must be fabricated before the cross-linking process, since the cross-linked EVA layer is difficult if not impossible to seal (this renders the manufacturing process very inefficient); and 2) the radiation dose required for sufficient cross-linking also releases significant quantities of acetic acid—a by-product of the radiation exposure. Since the HDPE presents a barrier to gas transmission, the trapped acetic acid can render the fluid contents quite acidic—a very undesirable outcome.

U.S. Pat. No. 4,643,926 assigned to W. R. Grace discloses fabricating a medical solution container from a multilayered material where, in certain embodiments, the layer intended to be heat sealed is constructed with polypropylene as the main ingredient. Since it is well known that polypropylenes undergo chain scission when exposed to radiation, the heat seal layer remained thermoplastic and capable of being heat-sealed to similar surfaces. Therefore, the entire multilayer film can be heat-sealed and survive autoclaving. However, the complexity of the multilayer construction and the possible need of washing and incorporating acid scavenging compounds in the film (See US Pat. No. 5,445,893) to remove the acidic by-products of irradiating EVA renders the process quite complicated and the cost very high. Further, since the film is constructed of several very dissimilar materials, process recycling of the edge trim and other film scraps is very difficult and impractical without greatly reducing the optical and mechanical properties.

U.S. Pat. No. 5,055,328 discloses a multilayer differentially cross-linked film where the heat-sealed layer contains additional antioxidants to retard cross-linking and to facilitate heat-sealing post cross-linking. Likewise, Canadian Patent 1,125,229 discloses another differential cross-linked multilayer film where the outer layer contains a cross-link enhancer. However, these constructions are all multilayer constructions and do not address the issue of self adhesion during autoclaving.

U.S. Pat. No. 4,724,176 to Sun discloses a multilayer, oriented, heat shrinkable container with a radiation cross-linked outer layer and, by controlling the irradiation process, a non cross-linked inner seal layer. The inner and outer layers can be of EVA copolymers. This container is designed to shrink upon application of heat, and, therefore, would be unsuitable for a container that must maintain substantially its entire volume after an autoclave process.

The main objective of the present invention is to provide polymeric materials that are, overall, superior to those materials, of which we are aware, which have been heretofore known in the art or have been commercially used or marketed. The properties of such materials include flexibility, optical transparency for visual inspection, and sufficient thermal resistance to withstand a steam sterilization process at temperatures up to 121° C. without experiencing significant distortion or self adhesion. The materials should also be non-oriented, non-adherent and capable of being sealed using heat sealing techniques. The materials should also be substantially free of low molecular weight leachable additives, and capable of safe disposal by incineration without the generation of significant amounts of corrosive inorganic acids. Finally, the material should serve as a cost-effective alternative to various PVC formulations currently being used for medical devices.

U.S. Pat. No. 5,879,768 discloses a pouch for packaging flowable materials fabricated from a material having a seal layer of a polymeric composition comprising: (A) 10 to 100 percent of a mixture of (1) from 5 to 95% of at least one

homogeneously branched substantially linear ethylene/ α -olefin interpolymers, and (2) from 5 to 95% of high pressure low density polyethylene having a density from 0.916-0.930 g/cc; and (B) from 0-90% of one polymer selected from the group consisting of an ultra low density polyethylene, a linear low density polyethylene, a high pressure low density polyethylene, an ethylene vinyl acetate copolymer, and a homogeneously branched linear ethylene polymer. The '768 Patent does not disclose exposing this blend to radiation nor does it disclose blending the homogeneously branched, substantially linear ethylene/ α -olefin interpolymers with polypropylene.

When more than one polymer is blended to form an alloying composition, it is difficult to achieve all of the above objectives simultaneously. For example, many alloys produce significant light scattering; thus, they fail to meet the optical clarity objective. The light scattering intensity (measured by haze) depends on the domain size of components in the micrometer (μ) range, and the proximity of the refractive indices of the components. As a general rule, the selection of components that can be satisfactorily processed into very small domain sizes, and yet with a minimum of refractive index mismatches, is a difficult task. The present invention is provided to solve these and other problems.

SUMMARY OF THE INVENTION

The present invention provides a non PVC, non oriented, multilayer film. The film has at least a first layer and a second layer adhered to one another. The first layer is a blend of a first and a second component. The first component is selected from the group of: (1) ethylene and α -olefin interpolymers having a density of less than about 0.915 g/cc, (2) ethylene and lower alkyl acrylate interpolymers, (3) ethylene and lower alkyl substituted alkyl acrylate interpolymers and (4) ionic polymers, commonly referred to as ionomers. The second component is selected from one or more of the following: (1) propylene containing polymers, (2) butene containing polymers, (3) polymethylpentene containing polymers, (4) cyclic olefin containing polymers and (5) bridged polycyclic hydrocarbon containing polymers. The second component is present in an amount by weight of the blend from about 35% to about 19%.

The film has a modulus of elasticity when measured in accordance with ASTM D882 of less than about 60,000 psi, an internal haze when measured in accordance with ASTM D1003 of less than about 25%, self adhesion ranking greater than about 2 as defined below, slight or no adhesion to overpouch materials, has a sample creep at 120° C. at about 27 psi loading of less than or equal to 150%, and the film can be heat sealed into a container having seals wherein the seals remain intact when a liquid filled container is autoclaved at 121° C. for one hour.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross-sectional view of a monolayer film of the present invention;

FIG. 2 is a cross-sectional view of a multiple layered film of the present invention;

FIG. 3 is a material container fabricated from a film of the present invention;

FIG. 4 is an I.V. fluid administration set;

FIG. 5 is a peritoneal dialysis container and tubing set; and

FIG. 6 is a dual chamber bag with a peelable seal separating the chambers.

The present invention is susceptible of embodiments in many different forms. Preferred embodiments of the invention are disclosed with the understanding that the present disclosure is to be considered as an exemplification of the principles of the invention and is not intended to limit the broad aspects of the invention to the embodiments illustrated.

I. Polymer Blends and Monolayer Films Therefrom

FIG. 1 shows a monolayer film 10 of the present invention. The monolayer film 10 is fabricated from a polymer blend having a first component and a second component. The first component is selected from the group of: (1) ethylene and α -olefin interpolymers having a density of less than about 0.915 g/cc, (2) ethylene and lower alkyl acrylate interpolymers, (3) ethylene and lower alkyl substituted alkyl acrylate interpolymers and (4) ionic polymers, commonly referred to as ionomers. The first component is present in an amount from about 99% to about 55% by weight of the blend, more preferably from about 60%-85% and most preferably from about 65%-80%.

The second component is selected from the group consisting of: (1) propylene containing polymers, (2) butene containing polymers, (3) polymethyl pentene containing polymers, (4) cyclic olefin containing polymers and (5) bridged polycyclic hydrocarbon containing polymers. The second component is present in an amount by weight of the blend from about 45% to about 1%, more preferably from about 15%-40% and most preferably from about 20%-35%.

The film has a modulus of elasticity when measured in accordance with ASTM D882 of less than about 60,000 psi, an internal haze when measured in accordance with ASTM D1003 of less than about 25%, self adhesion ranking greater than about two (as defined below), slight or no adhesion to overpouch materials, has a sample creep at 120° C. at about 27 psi loading of less than or equal to 150%, and the film can be heat sealed into a container having seals wherein the seals remain intact when a liquid filled container is autoclaved at 121° C. for one hour.

As used herein, the term "interpolymer" includes copolymers, terpolymers either random or block.

Suitable ethylene and α -olefin interpolymers preferably have a density, as measured by ASTM D-792 of less than about 0.915 g/cc and are commonly referred to as very low density polyethylene (VLDPE), ultra low density ethylene (ULDPE) and the like. The α -olefin should have from 3-17 carbons, more preferably from 4-12 and most preferably 4-8 carbons. In a preferred form of the invention, the ethylene and α -olefin copolymers are obtained using single site catalysts. Suitable single site catalyst systems, among others, are those disclosed in U.S. Pat. Nos. 5,783,638 and 5,272,236. Suitable ethylene and α -olefin copolymers include those sold by Dow Chemical Company under the AFFINITY tradename, Dupont-Dow under the ENGAGE tradename and Exxon under the EXACT and PLASTOMER tradenames.

The term "lower alkyl acrylates" refers to comonomers having the formula set forth in Diagram 1:

Diagram 1



The R group refers to alkyls having from 1 to 17 carbons. Thus the term "lower alkyl acrylates" includes but is not limited to methyl acrylate, ethyl acrylate, butyl acrylate and the like.

The term "alkyl substituted alkyl acrylates" refers to comonomers having the formula set forth in Diagram 2:

Diagram 2



R₁ and R₂ are alkyls having 1-17 carbons and can have the same number of carbons or have a different number of carbons. Thus, the term "alkyl substituted alkyl acrylates" includes but is not limited to methyl methacrylate, ethyl methacrylate, methyl ethacrylate, ethyl ethacrylate, butyl methacrylate, butyl ethacrylate and the like.

Suitable propylene containing polymers include those selected from the group consisting of homopolymers of polypropylene, copolymers and terpolymers of propylene with one or more comonomers selected from α -olefins having from 2-17 carbons. Suitable polypropylene copolymers and terpolymers include random or block propylene and ethylene copolymers or random or block propylene/ethylene/butene terpolymers. Suitable propylene and α -olefin copolymers are sold by Montell under the tradename PRO FAX, PRO FAX ULTRA and CATALLOY.

The present invention also contemplates using blends of propylene containing polymers as the second component of the blend. In a preferred form of the invention the blends include at least a first propylene containing polymer and a second propylene containing polymer. The first propylene containing polymer and the second propylene containing polymer can be selected from the propylene homopolymer, copolymers and terpolymers set forth above. In a preferred form of the invention the first propylene containing polymer differs from the second propylene containing polymer in at least one of two ways. The first difference is the first propylene containing polymer preferably should have a melt flow rate of from about 3 times greater and more preferably from about 5 times greater than the melt flow rate of the second propylene containing polymer. The second difference is the first propylene containing polymer preferably has a melting point from at least about 5° C. higher and more preferably from at least about 10° C. higher than that of the second propylene containing polymer. The melting point is measured in accordance with ASTM D3417 (Enthalpies of Fusion and Crystallization of Polymers by Differential Scanning Calorimetry). The first propylene containing polymer can differ from the second propylene containing polymer by the first difference, by the second difference or by both.

Suitable homopolymer and copolymers of cyclic olefins and bridged polycyclic hydrocarbons and blends thereof can be found in U.S. Pat. Nos. 5,218,049, 5,854,349, 5,863,986, 5,795,945, 5,792,824; and European Patent numbers EP 0 291,208, EP 0 283,164, EP 0 497,567 which are incorporated in their entirety herein by reference and made a part hereof.

In a preferred form of the invention, suitable cyclic olefin monomers are monocyclic compounds having from 5 to about 10 carbons in the ring. The cyclic olefins can be selected from the group consisting of substituted and unsubstituted cyclopentene, cyclopentadiene, cyclohexene, cyclohexadiene, cycloheptene, cycloheptadiene, cyclooctene, cyclooctadiene. Suitable substituents include lower alkyl, acrylate derivatives and the like.

In a preferred form of the invention, suitable bridged polycyclic hydrocarbon monomers have two or more rings and more preferably contain at least 7 carbons. The 20 rings can be substituted or unsubstituted. Suitable substituents include lower alkyl, aryl, aralkyl, vinyl, allyloxy, (meth) acryloxy and the like. The bridged polycyclic hydrocarbons are selected from the group consisting of those disclosed in the above incorporated patents and patent applications. Suitable bridged polycyclic hydrocarbon containing polymers are sold by Ticona under the tradename TOPAS, by Nippon Zeon under the tradename ZEONEX and ZEONOR, by Daiyoku Gomu Seiko under the tradename CZ resin, and by Mitsui Petrochemical Company under the tradename APEL.

In a preferred form of the present invention the film will have the following physical characteristics: (1) a modulus of elasticity when measured in accordance with ASTM D882 of less than about 60,000 psi, (2) an internal haze when measured in accordance with ASTM D1003 of less than about 25%, (3) self adhesion ranking greater than about two as defined below, (4) no adhesion to overpouch materials, (5) has a sample creep at 120° C. at about 27 psi loading of less than or equal to 150%, and (6) the film can be heat sealed into a container having seals wherein the seals remain intact when a liquid-filled container is autoclaved at 121° C. for one hour.

The film is also sufficiently flexible to construct flowable material containers. The film has a modulus of elasticity of less than about 60,000 psi, more preferably less than about 40,000 psi, even more preferably less than about 30,000 and most preferably less than about 20,000 psi when measured in accordance with ASTM D-882. When the flowable material container is an I.V. container it is desirable the container collapse or substantially collapse upon draining, and, therefore, should have a modulus of elasticity of less than about 40,000 psi, more preferably less than about 30,000 psi, and even more preferably less than about 20,000 when measured in accordance with ASTM D-882.

For the purposes of this invention, self adhesion is defined as the tendency of the film to adhere to itself during autoclaving. This property can be determined with the following test. Film strips are cut 8"x2", with the larger dimension in the machine direction. These strips are rolled into 2" long tubes approximately 0.5" in diameter. The wound film is held in place by compressing the film layers together at one end with a paper clip. The tubes are then placed in a steam autoclave at 121° C. for 30 minutes. The samples are allowed to cool for at least one hour. The film is then unwound. The resistance to unwinding and relative damage to the film is ranked as shown in Table 1 as follows:

TABLE 1
Rank Observed Result 1 The film cannot be unwound without destroying the film. 2 The film is difficult to peel and significant surface damage results. 3 Some resistance to peeling and minor surface damage are noted. 4 Slight resistance to peeling noted with little or no surface damage. 5 No peel resistance and no surface damage noted. Ranks are determined by three or more individuals and recorded as an average.

Adhesion to over pouch materials is determined by the following qualitative test. One inch wide strips of film are sealed into typical over pouch bags (medium or high density polyethylene). The over pouch bag is then placed into a laboratory autoclave at 252° F. and 24.5 psig gauge pressure for one hour. After autoclaving, the bags are cut open and the strips removed. If the films separate from the over pouch without leaving damage marks on the film surface, a ranking of no adhesion (N) is given. If the film separation produces visible damage, a ranking is given (Y) indicating that tack to the over pouch is present. A ranking to indicate slight adhesion (S) can also be given.

Creep properties were determined at 120° C. by clamping film strips having a thickness from about 5 mils to about 15 mils in a temperature controlled oven and loading with weights to produce a stress of about 27 psi. After loading for 40 minutes, the film strips were removed and the dimensional changes in a pre-marked one inch gap were recorded.

The film is capable of being sealed using standard heat sealing techniques. An adequate heat seal is formed when a fluid container, such as the one shown in FIG. 3, is fabricated from the film by sealing peripheral edges to define a centrally disposed fluid chamber. The container is filled with water and subjected to a standard autoclave sterilization process. Adequate heat seals remain intact upon completion of the autoclave cycle.

The films of the present invention have a haze of less than about 25% and most preferably less than about 15% when measured in accordance with ASTM D1003. For the purposes of this invention, internal haze is defined as the haze value measured when both film surfaces have been wetted with isopropyl alcohol.

II. Polymer and Film Processing

To produce the film of the present invention, raw materials are fed into an extrusion hopper at the desired mix ratio employing weight feeders. The materials are extruded using an extrusion die to produce a mono-layer film. The film is irradiated with a suitable energy source and then sealed to form a fluid container. It is also contemplated exposing the blend to radiation before extrusion. The raw materials can also be pre-compounded before extrusion employing a single screw, twin screw or other compounding methods familiar to those skilled in the art.

The preferred method of irradiating the film is to expose it to an electron beam with beam energy from about 150 Kev-10 Mev, more preferably from 200-300 Kev and a dosage from about 20 kGys to about 200 kGys and more preferably from about 60-150 kGys. Alternatively, the film can be crosslinked using methods known to those skilled in the arts. Methods for crosslinking employed in the industry include exposure to ionizing radiation (gamma, beta, ultraviolet, etc.) and chemical (peroxides and condensing reactions).

To reduce or minimize the oxidative degradation of the film during and subsequent to electron beam exposure, it is desirable to reduce the partial pressure of oxygen in the area surrounding the film being exposed to the radiation. The oxygen partial pressure may be reduced by applying a vacuum or by applying another gas such as nitrogen under pressure or other known techniques for accomplishing this goal. In a preferred form of the invention the oxygen concentration during a nitrogen flush is less than about 100 ppm and more preferably less than about 40 ppm.

III. Multilayer Films

FIG. 2 shows an example of a multilayer film 20 including layer 12 of the mono-layer described above. In a preferred

form of the invention the mono-layer shall be the seal layer. The multilayer film 20 can include any additional layer 14 or combination of additional layers selected from layers such as a skin layer, a radio frequency susceptible layer, a water vapor barrier layer, a gaseous barrier layer, a scrap layer, a seal layer and a core layer to name a few.

The skin layer can be added to increase the scuff resistance of the film. The skin layer can be an olefin material, such as homopolymers and copolymers of propylene and ethylene. The skin layer may also be a polyester, copolyester, polyamide or copolyamide. The term "copolyester" and the like is applied to polyesters synthesized from more than one diol and a dibasic acid. Copolyesters as used herein may also be characterized as copolymers of polyethers and polyethylene terephthalate. More preferably copolyesters as used herein may be characterized as polymeric materials derived from 1,4 cyclohexane dimethanol, 1,4-cyclohexane dicarboxylic acid, and polytetramethylene glycol ether, or equivalents of any of the above, as reactants

Suitable water vapor barriers include but are not limited to HDPE, MDPE and polyester (PET, PBT, PEN, etc.)

Suitable gaseous barriers are those that inhibit the passage of oxygen, carbon dioxide or other gasses. Suitable gas barriers include but are not limited to polyesters and polyamides.

Scrap material generated prior to irradiation can be incorporated into one or more layers.

IV. Flowable Material Containers

FIG. 3 shows a flowable material container and particularly an I.V. container 30. FIG. 4 shows an I.V. administration set 40 and FIG. 5 shows a peritoneal dialysis set 50. The present invention further contemplates fabricating medical tubing from the blends of the present invention. It is contemplated that the radiation treatment of tubing will differ from films due to the increased thickness and round shape of tubing but tubing can be effectively treated within the radiation energy ranges set forth above for the film. What is meant by "flowable material" is a material that will flow by the force of gravity. Flowable materials therefore include both liquid items and powdered or granular items and the like. The container 30 has sidewalls 32 placed in registration and sealed along peripheral edges to define a chamber 34 for containing flowable materials such as fluids or granular material. For containers made through blow molding only or blow extrusion longitudinal edges would be sealed. A port tube 36 or multiple port tubes are provided to fill and empty the contents of the container 30. The sidewalls and port tube can be fabricated from one of the monolayer or multilayered films set forth above. Surprisingly, the medical articles fabricated from the films and blends described above can be heat sealed even though the film has been irradiated with electron beam radiation.

Heat seals can be achieved using standard heat sealing techniques known to those skilled in the art.

V. Dual Chamber Peelable Seal Containers

FIG. 6 shows a dual chamber container 70 having a first chamber 72 and a second chamber 74 separated by a peelable seal 76. The container sidewalls 75 are fabricated from one of the polymer blends, monolayer films or multiple layered films set forth above. Dual chamber containers can be used for numerous applications such as separately housing two components for mixing later. The components can be liquid or powdered. The peelable seal can be created by modifying the sealing conditions such that the peelable seal 76 is capable of being ruptured by applying a force to a sidewall 75 of the container. Typically, one of the chambers will contain a liquid. By pressing on the container sidewall 75 over the liquid containing chamber the liquid contents will flow toward the peelable seal 76 and by applying sufficient pressure the seal 76 will rupture to allow mixing of the components stored in the separate chambers.

While FIG. 6 shows only one peelable seal 76, it is contemplated that numerous peelable seals could be provided to create numerous chambers. Further, FIG. 6 shows the peelable seal running between lateral edges. It is also contemplated that the peelable seals could extend between longitudinal edges or simply around an area not intersecting the permanent peripheral seam 79 to define a chamber.

The peelable seal 76 may be created simultaneously with sealing the peripheral sidewalls or before or after the creation of the permanent peripheral seals. The peelable seal 76 can be created by controlling sealing conditions. Peelable seals can be created with the application of lower temperature and pressure than employed to provide the permanent peripheral seal or by shortening the sealing times from that used to provide the permanent seal or the like. Further enhancement of the peel characteristics can be obtained with localized modification of the film surface characteristics (corona or other suitable treatment).

It is contemplated that the container can be sealed using ultrasonic welding techniques, conduction heat sealing techniques and other sealing techniques well known in the art.

VI. Examples

The blends identified in the table below were fabricated into a monolayer film using an extrusion process. The film was exposed to electron beam radiation having an acceleration voltage of from 200 Kev to 300 Kev for a dose set forth in the table that follows:

[illegible]

-continued

FORMULA	1	2	3	4	5	6	7	8	9	10
Self adhesion rank —										
100 kGy	1	2	3.7	4	1	NA	1	2	4	NA
150 kGy	1	2	4.5	5	1	NA	1.3	2.3	3.3	NA
200 kGy	1	3.3	4.7	5	1	1.7	2	2	4	NA
Tack to over pouch —										
100 kGy	Y	S	N	N	Y	NA	Y	S	N	NA
150 kGy	Y	S	N	N	Y	NA	Y	N	N	NA
200 kGy	Y	S	N	N	Y	NA	Y	N	N	NA
120° C. Creep (%)										
0 kGy	NA	NA	NA	NA	NA	NA	Melts	NA	550	NA
100 kGy	200	138	88	41	263	NA	216	98	28	NA
150 kGy	63	38	31	18	43	NA	31	25	13	NA
200 kGy	25	13	16	16	21	22	16	9	22	NA
Autoclavability										
100 kGy	NA	NA	Y	Y	NA	NA	NA	Y	Y	Y
150 kGy	NA	NA	Y	Y	NA	NA	NA	Y	Y	Y
Internal Haze (ASTM D1003)	1	1.2	1.6	2.8	2.7	2.7	3.5	4.3	4.8	2.2
Tensile modulus (psi) (ASTM D882)	2860	3800	6650	16260	6110	NA	12830	19810	28820	21060

Dow Affinity PL 1880 is a ULDPPE having a density of 0.902 g/cc.

DuPont Dow Engage 8003 is a ULDPPE having a density of 0.885 g/cc.

Exxon PP305GE1 is a homopolymer of propylene (MFR 440).

Montell SA-861 is a propylene and ethylene copolymer (MFR 6.5).

Montell SA 982 is a propylene and ethylene copolymer (MFR 100).

"NA" means not available.

We claim:

1. A multilayer film formed by a coextrusion process, the film comprising:

an outer first layer of a blend of a first component selected from the group consisting of: (1) ethylene and α -olefin copolymers having a density of less than 0.915 g/cc, (2) ethylene copolymerized with C_3 - C_{17} alkyl acrylates, (3) ethylene copolymerized with C_3 - C_{17} alkyl substituted alkyl acrylates and (4) ionomers, the first component being present in an amount greater than 55% by weight of the blend, a second component in an amount by weight of the blend less than 45% and is selected from the group consisting of: (1) propylene containing polymers, (2) polybutene polymers, (3) polymethylpentene polymers, (4) cyclic olefin containing polymers and (5) bridged polycyclic hydrocarbon containing polymers;

a second layer selected from the group consisting of propylene homopolymers, propylene copolymers, ethylene homopolymers, ethylene copolymers, polyesters, copolymers, polyamides and copolyamides; and,

the film is non-oriented has a modulus of elasticity when measured in accordance with ASTM D882 of less than 60,000 psi, an internal haze when measured in accordance with ASTM D1003 of less than about 25%, an internal adhesion ranking of greater than 2 such that the film can be formed into a roll and autoclaved and can be unrolled after autoclaving, a sample creep at 120° C. under 27 psi loading of less than or equal to 150% for a film having a thickness of from about 5 mils to about 15 mils, and the film can be heat sealed into a container having seals wherein the seals remain intact when the container is autoclaved at 121° C. for one hour.

2. The film of claim 1 wherein the propylene containing polymer is selected from the group consisting of a homopolymer of polypropylene, random copolymers of propylene, block copolymers of propylene, random terpolymers of propylene, and block terpolymers of propylene, wherein the copolymers and terpolymers of propylene have a comonomer selected from α -olefins having from 2 to about 17 carbons.

3. The film of claim 2 wherein the second component is a propylene and ethylene copolymer having an ethylene content of from 1-6% by weight of the copolymer.

4. The film of claim 2 wherein the second component is a blend of a first propylene containing polymer and a second propylene containing polymer.

5. The film of claim 4 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate wherein the first melt flow rate is about 3 times greater than the second melt flow rate.

6. The film of claim 4 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate wherein the first melt flow rate is about 5 times greater than the second melt flow rate.

7. The film of claim 4 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second melting point temperature wherein the first melting point temperature is higher than the second melting point temperature by at least 5° C.

8. The film of claim 4 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second melting point temperature wherein the first melting point temperature is higher than the second melting point temperature by at least 10° C.

9. The film of claim 4 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate different than the first melt flow rate.

10. The film of claim 4 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second melting point temperature different than the first melting point temperature.

11. The film of claim 1 wherein the cyclic olefin has from 5 to about 10 carbons in the ring.

12. The film of claim 11 wherein the cyclic olefin is selected from the group consisting of cyclopentene, cyclopentadiene, cyclohexene, cyclohexadiene, cycloheptene, cycloheptadiene, cyclooctene, and cyclooctadiene.

13. The film of claim 12 wherein the cyclic olefin has a substituent selected from the group consisting of C_1 - C_{17} alkyl, and acrylate derivatives.

14. The film of claim 1 wherein the bridged polycyclic hydrocarbon has at least 7 carbons.

15. The film of claim 14 wherein the bridged polycyclic hydrocarbon is selected from the group consisting of polycyclic hydrocarbons having at least 7 carbons.

16. The film of claim 1 wherein the α -olefin has from 3 to 17 carbons.

17. The film of claim 1 wherein the α -olefin has from 4 to 8 carbons.

18. The film of claim 17 wherein the ethylene and α -olefin copolymer is obtained using a single site catalyst.

19. The film of claim 1 wherein the blend is subjected to electron beam radiation in a dosage amount from about 20 kGy to about 200 kGy.

20. The film of claim 1 wherein the second layer is selected from the group consisting of a skin layer, a radio frequency susceptible layer, a water vapor barrier layer, a gaseous barrier layer, a scrap layer, a seal layer and a core layer.

21. A multiple layered film formed by coextrusion comprising:

an outer first layer of a first component selected from the group consisting of: (1) ethylene and α -olefin copolymers having a density of less than 0.915 g/cc, (2) ethylene copolymerized with C_1 - C_{17} alkyl acrylates, (3) ethylene copolymerized with C_1 - C_{17} alkyl substituted alkyl acrylates and (4) ionomers, the first component being present in an amount from about 99% to about 55% by weight of the blend, a second component in an amount by weight of the blend from about 45% to about 1% and is selected from the group consisting of: (1) propylene containing polymers, (2) polybutene polymers, (3) polymethylpentene polymers, (4) cyclic olefin containing polymers and (5) bridged polycyclic hydrocarbon containing polymers;

a second layer selected from the group consisting of a propylene homopolymer, propylene copolymers, an ethylene homopolymer, ethylene copolymers, polyesters, polyamides, polyamides and copolyamides; and,

wherein the film is non-oriented and subjected to electron beam radiation in a dosage amount from about 20 kGy to about 200 kGy.

22. The film of claim 21 wherein the film has a modulus of elasticity when measured in accordance with ASTM D882 of less than 60,000 psi, an internal haze when measured in accordance with ASTM D1003 of less than 25%, an internal adhesion ranking of greater than 2 such that the film

can be formed into a roll and autoclaved and can be unrolled after autoclaving, a sample creep at 120° C. under 27 psi loading of less than or equal to 150% for a film having a thickness of from about 5 mils to about 15 mils, and the film can be heat sealed into a container having seals wherein the seals remain intact when the container is autoclaved at 121° C. for one hour.

23. The film of claim 21 wherein the film is exposed to a oxygen partial pressure less than ambient conditions when exposed to the electron beam radiation.

24. The film of claim 21 wherein the propylene containing polymer is selected from the group consisting of a homopolymer of polypropylene, random copolymers of propylene, block copolymers of propylene, random terpolymers of propylene, and block terpolymers of propylene, wherein the copolymers and terpolymers of propylene have a comonomer selected from α -olefins having from 2 to about 17 carbons.

25. The film of claim 21 wherein the second component is a propylene and ethylene copolymer having an ethylene content of from 1-6% by weight of the copolymer.

26. The film of claim 21 wherein the second component is a blend of a first propylene containing polymer and a second propylene containing polymer.

27. The film of claim 26 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate wherein the first melt flow rate is about 3 times greater than the second melt flow rate.

28. The film of claim 26 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate wherein the first melt flow rate is about 5 times greater than the second melt flow rate.

29. The film of claim 26 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second melting point temperature wherein the first melting point temperature is higher than the second melting point temperature by at least 5° C.

30. The film of claim 26 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second melting point temperature wherein the first melting point temperature is higher than the second melting point temperature by at least 10° C.

31. The film of claim 26 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate different than the first melt flow rate.

32. The film of claim 26 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second melting point temperature different than the first melting point temperature.

33. The film of claim 21 wherein the cyclic olefin has from 5 to about 10 carbons in the ring.

34. The film of claim 33 wherein the cyclic olefin is selected from the group consisting of cyclopentene, cyclopentadiene, cyclohexene, cyclohexadiene, cycloheptene, cycloheptadiene, cyclooctene, and cyclooctadiene.

35. The film of claim 34 wherein the cyclic olefin has a substituent selected from the group consisting of C_1 - C_{17} alkyl, and acrylate derivatives.

36. The film of claim 21 wherein the bridged polycyclic hydrocarbon has at least 7 carbons.

37. The film of claim 36 wherein the bridged polycyclic hydrocarbon is selected from the group consisting of polycyclic hydrocarbons having at least 7 carbons.

38. The film of claim 21 wherein the α -olefin has from 3 to 17 carbons.

39. The film of claim 38 wherein the ethylene and α -olefin copolymer is obtained using a single site catalyst.

40. The film of claim 21 wherein the α -olefin has from 4 to 8 carbons.

41. The film of claim 21 wherein the second layer is selected from the group consisting of a skin layer, a radio frequency susceptible layer, a water vapor barrier layer, a gaseous barrier layer, a scrap layer, a seal layer and a core layer.

42. A multilayer film comprising:

an outer first layer of a blend of a first component of an ethylene and α -olefin copolymer having a density of less than 0.915 g/cc and present in an amount greater than 55% by weight of the blend, a second component in an amount by weight of the blend of less than 45% and is selected from the group consisting of: (1) propylene containing polymers, (2) polybutene polymers, (3) polymethylpentene polymers, (4) cyclic olefin containing polymers and (5) bridged polycyclic hydrocarbon containing polymers;

a second layer attached to the first layer and, being selected from the group consisting of propylene homopolymers, propylene copolymers, ethylene homopolymers, ethylene copolymers, polyesters, copolyesters, polyamides and copolyamides; and

the film is non-oriented and has a modulus of elasticity when measured in accordance with ASTM D882 of less than 60,000 psi, an internal haze when measured in accordance with ASTM D1003 of less than 25%, an internal adhesion ranking of greater than 2 such that the film can be formed into a roll and autoclaved and can be unrolled after autoclaving, a sample creep at 120° C. under 27 psi loading of less than or equal to 150% for a film having a thickness of from about 5 mils to about 15 mils, and the film can be heat sealed into a container having seals wherein the seals remain intact when the container is autoclaved at 121° C. for one hour.

43. The film of claim 42 wherein the ethylene and α -olefin copolymer is obtained using a single-site catalyst.

44. A multilayer film comprising:

an outer first layer of a blend of an ethylene and α -olefin copolymers obtained using a single-site catalyst and having a density of less than 0.915 g/cc and present from about 99% to about 55% by weight of the blend, a second component in an amount by weight of the blend from about 45% to about 1% and is selected from the group consisting of: (1) propylene containing polymers, (2) polybutene polymers, (3) polymethylpentene polymers, (4) cyclic olefin containing polymers and (5) bridged polycyclic hydrocarbon containing polymers;

a second layer attached to the first layer and, being selected from the group consisting of propylene homopolymers, propylene copolymers, ethylene homopolymers, ethylene copolymers, polyesters, copolyesters, polyamides and copolyamides; and,

the film is non-oriented and has a modulus of elasticity when measured in accordance with ASTM D882 of less than 60,000 psi, an internal haze when measured in accordance with ASTM D1003 of less than 25%, an internal adhesion ranking of greater than about 2 such

that the film can be formed into a roll and autoclaved and can be unrolled after autoclaving, a sample creep at 120° C. under 27 psi loading of less than or equal to 150% for a film having a thickness of from about 5 mils to about 15 mils, and the film can be heat sealed into a container having seals wherein the seals remain intact when the container is autoclaved at 121° C. for one hour.

45. A multilayer film comprising:

a first layer of a blend of a first component selected from the group consisting of: (1) ethylene and α -olefin copolymers having a density of less than 0.915 g/cc, (2) ethylene copolymerized with C_1 - C_{17} alkyl acrylates, (3) ethylene copolymerized with C_1 - C_{17} alkyl substituted alkyl acrylates and (4) ionomers, the first component being present in an amount from about 99% to about 55% by weight of the blend, a second component in an amount by weight of the blend from about 45% to about 1% and consists of a blend of a first propylene containing polymer and a second propylene containing polymer;

a second layer attached to the first layer and being selected from the group consisting of propylene homopolymers, propylene copolymers, ethylene homopolymers, ethylene copolymers, polyesters, copolyesters, polyamides and copolyamides; and,

the film has a modulus of elasticity when measured in accordance with ASTM D882 of less than 60,000 psi, an internal haze when measured in accordance with ASTM D1003 of less than 25%, an internal adhesion ranking of greater than 2 such that the film can be formed into a roll and autoclaved and can be unrolled after autoclaving, a sample creep at 120° C. under 27 psi loading of less than or equal to 150% for a film having a thickness of from about 5 mils to about 15 mils, and the film can be heat sealed into a container having seals wherein the seals remain intact when the container is autoclaved at 121° C. for one hour.

46. The film of claim 45 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate wherein the first melt flow rate is about 3 times greater than the second melt flow rate.

47. The film of claim 45 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate wherein the first melt flow rate is about 5 times greater than the second melt flow rate.

48. The film of claim 45 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second melting point temperature wherein the first melting point temperature is higher than the second melting point temperature by at least 5° C.

49. The film of claim 45 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second melting point temperature wherein the first melting point temperature is higher than the second melting point temperature by at least 10° C.

50. The film of claim 45 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate different than the first melt flow rate.

51. The film of claim 45 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second

melting point temperature different than the first melting point temperature.

52. A multiple layered film comprising:

an outer first layer of a first component selected from the group consisting of: (1) ethylene and α -olefin copolymers having a density of less than 0.915 g/cc, (2) ethylene copolymerized with C_7 - C_{17} alkyl acrylates, (3) ethylene copolymerized with C_7 - C_{17} alkyl substituted alkyl acrylates and (4) ionomers, the first component being present in an amount from about 99% to about 55% by weight of the blend, a second component in an amount by weight of the blend from about 45% to about 1% and consists of a blend of a first propylene containing polymer and a second propylene containing polymer;

a second layer attached to the first layer, the second layer being selected from the group consisting of propylene homopolymers, propylene copolymers, ethylene homopolymers, ethylene copolymers, polyesters, copolyesters, polyamides and copolyamides; and,

wherein the film is non-oriented and is subjected to electron beam radiation in a dosage amount from about 20 kGy to about 200 kGy.

53. The film of claim 52 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate wherein the first melt flow rate is about 3 times greater than the second melt flow rate.

54. The film of claim 52 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate wherein the first melt flow rate is about 5 times greater than the second melt flow rate.

55. The film of claim 52 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second melting point temperature wherein the first melting point temperature is higher than the second melting point temperature by at least about 5° C.

56. The film of claim 52 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second melting point temperature wherein the first melting point temperature is higher than the second melting point temperature by at least about 10° C.

57. The film of claim 46 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate different than the second melt flow rate.

58. The film of claim 46 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second melting point temperature different than the first melting point temperature.

* * * * *

EXHIBIT E



US006969483B1

(12) United States Patent
Woo et al.**(10) Patent No.: US 6,969,483 B1**
(45) Date of Patent: *Nov. 29, 2005**(54) AUTOCLAVABLE, NON-ADHERENT, HEAT SEALABLE POLYMER BLENDS FOR FABRICATING MONOLAYER AND MULTIPLE LAYERED FILMS****FOREIGN PATENT DOCUMENTS**

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- (*) Notice:**
- Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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- (52) U.S. Cl.**
- 264/405; 428/500; 525/191; 525/201; 525/240

- (58) Field of Search**
- 525/240, 201, 525/191; 264/405; 428/500

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(57) ABSTRACT

The present invention provides a polymer blend for fabricating monolayer films or a layer within a multilayer film. The blend has a first component and a second component. The first component is selected from the group of: (1) an ethylene and α -olefin copolymer having a density of less than about 0.915 g/cc, (2) lower alkyl acrylates, (3) lower alkyl substituted alkyl acrylates and (4) ionomers. The first component should be present in an amount from about 99% to about 55% by weight of the blend. The second component in an amount by weight of the blend from 45% to about 1% and consists of one or more polymers of the group: (1) propylene containing polymers, (2) polybutene polymers, (3) polymethylpentene polymers, (4) cyclic olefin containing polymers and (5) bridged polycyclic hydrocarbon containing polymers. When the blend is fabricated into a film it has a modulus of elasticity when measured in accordance with ASTM D882 of less than about 60,000 psi, an internal haze when measured in accordance with ASTM D1003 of less than about 25%, an internal adhesion ranking of greater than about two, a sample creep at 120° C. under 27 psi loading of less than or equal to 150% for a film having a thickness from about 5 mils to about 15 mils, and the film being capable of being heat sealed into a container having seals wherein the seals remain intact when the container is autoclaved at 121° C. for one hour.

79 Claims, 3 Drawing Sheets

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FIG. 1



FIG. 2

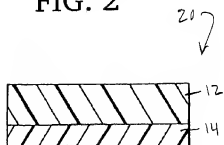


FIG. 3

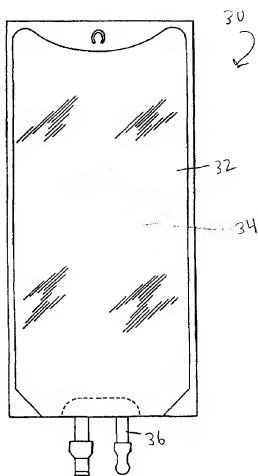


FIG. 4

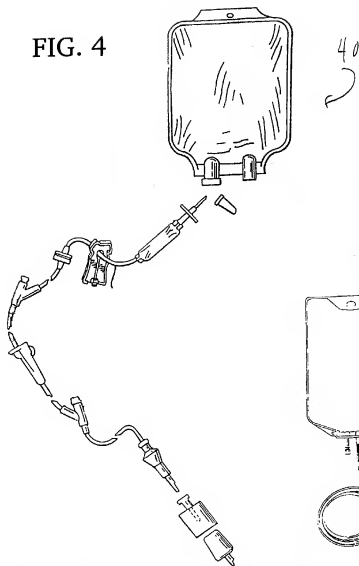


FIG. 5

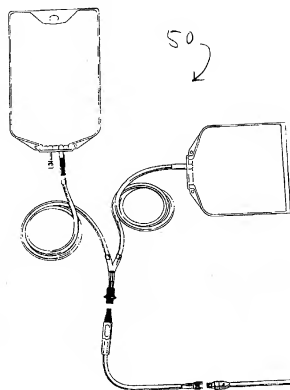
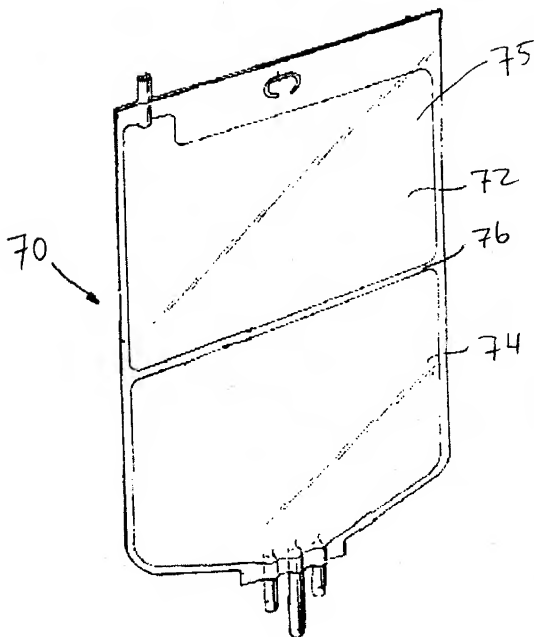


FIG. 6



AUTOCLAVABLE, NON-ADHERENT, HEAT SEALABLE POLYMER BLENDS FOR FABRICATING MONOLAYER AND MULTIPLE LAYERED FILMS

TECHNICAL FIELD

The present invention relates generally to polymer blends for fabricating films and more particularly films that have low distortion and are non-adherent upon steam sterilization, are heat sealable and are suitable for fabricating into flexible medical containers.

BACKGROUND OF THE INVENTION

In the medical field, where beneficial agents are collected, processed and stored in containers, transported, and ultimately delivered through tubes by infusion to patients to achieve therapeutic effects, materials which are used to fabricate the containers must have a unique combination of properties. For example, visual inspection of solutions for particulate contamination requires an optically transparent container. The material which forms the wall must be sufficiently flexible to infuse a solution by collapsing the container walls, without introducing air into the container. The material must maintain its flexibility and toughness over a wide range of temperatures. The material must maintain its flexibility and toughness at low temperatures because some solutions, for example, certain premixed drug solutions, are stored and transported in containers at temperatures such as -25 to -30° C. to minimize the drug degradation. The material must also be functional and resist distortion at high temperatures to withstand the heat of steam sterilization; a process which most medical fluid containers and nutritional products are subjected to prior to shipment. The sterilization process usually includes exposing the container to steam at temperatures typically 121° C. and at elevated pressures.

For ease of manufacture into useful articles, it is desirable that the material be sealable using heat sealing techniques. The material therefore must maintain sufficient thermoplastic properties to melt upon heating.

A further requirement is to minimize the environmental impact upon the disposal of the article fabricated from the material after its intended use. For those articles that are disposed of in landfills, it is desirable to minimize or avoid the incorporation of low molecular weight leachable components to construct the article. Further benefits are realized by using a material that allows thermal reprocessing of scrap material produced during manufacturing.

For those containers which are disposed of through incineration to minimize biological hazards, it is desirable to use a material that minimizes or eliminates the formation of environmentally undesirable and corrosive inorganic acids.

It is also desirable that the material be free from or have a low content of low molecular weight additives such as plasticizers, stabilizers and the like which could be released into the medications or biological fluids.

Due to its ability to meet a wide variety of functional requirements, flexible polyvinyl chloride (PVC) has frequently been the material of choice for medical bag applications. PVC also offers the distinct advantage of being one of the most cost-effective materials for constructing devices that meet the above requirements. However, PVC has a number of disadvantages in the marketplace. These disadvantages include incompatibility of PVC compounds with certain drugs, concerns regarding chlorine content and its effects on the environment and a growing negative market

perception of PVC in general. Thus, many materials have been devised to replace PVC. However, most alternate materials are too expensive to implement and still do not meet all of the above requirements.

Polyolefins and polyolefin alloys have been developed which meet many of the requirements of medical containers and tubing, without the disadvantages associated with PVC. Polyolefins typically are compatible with medical applications because they have relatively low extractability to fluids. Most polyolefins are environmentally sound as they do not generate harmful degradants upon incineration, and are suitable for thermoplastic recycling. Many polyolefins are cost effective materials that may provide an economic alternative to PVC. However, there are many hurdles to overcome to replace all the favorable attributes of PVC with a polyolefin.

For example, problems have been encountered in using certain polyolefins to fabricate medical tubing. Such tubing has been found to have poor surface characteristics so that it is readily susceptible to cutting, shredding or scoring when clamping the tubing using a slide clamp. Also, certain polyolefins that have favorable modulus attributes, such as ultra-low density polyethylenes, have melting point temperatures below that reached during an autoclave process.

It is well known that cross linking by chemical agents or by high energy ionizing radiation increases heat resistance of the polymer matrix. The chemical crosslinks are covalent bonds across separate polymer chains that greatly retard the tendency to deform and flow at high temperatures—even above the melting point of the polymer. For example, U.S. Pat. No. 4,465,487 assigned to Terumo discloses fabricating steam autoclavable medical containers by irradiating ethylene vinyl acetate copolymers with high energy (2 Mev) electron beams at doses between 50 kGy and 100 kGy to achieve gel contents of between 50% and 85%. The '487 Patent discloses that if the EVA sidewalls of the container are irradiated to achieve a gel content of about 50% or higher before being sealed together they are easily peeled apart. (Col. 4, lines 20-30). Accordingly, the '487 patent discloses irradiating the sidewalls of the container after sealing the container into a pouch leaving only a port area unsealed.

Similarly, U.S. Pat. No. 4,453,940 discloses fabricating medical containers from EVA and other materials. The '940 patent also discloses the step of increasing the autoclave resistance of EVA by cross-linking the material with high energy electron beam. The '940 patent warns that if the cross-linking exceeds 50% the use of heat sealing becomes impossible. (Col. 4, lines 27-35).

U.S. Pat. No. 4,401,536 discloses crosslinking semi-rigid containers composed of blends of polypropylene and EVA or EEA. This patent does not disclose the use of ethylene alpha olefins with polypropylene. It also discloses that irradiation before forming results in articles with poor heat sealability (Col. 4, lines 25-28).

U.S. Pat. Nos. 4,892,604 and 5,066,290 both assigned to the present assignee, disclose a medical container with a coextruded high density polyethylene skin layer and a core layer of an ethylene vinyl acetate copolymer having about 18% vinyl acetate content. After the container is fabricated by conventional radio frequency heat seal, the assembly is subjected to ionizing radiation of about 100 kGy from a high energy electron beam accelerator of about 5 Mev. The high density polyethylene layer acts as a moisture and gas transmission barrier to maintain the sterile fluid content at a relatively constant concentration as required by various pharmacopoeia of the world. However, several serious deficiencies were apparent in this material construction: 1) to

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fabricate a container from this material construction the container must be fabricated before the cross-linking process, since the cross-linked EVA layer is difficult if not impossible to seal (this renders the manufacturing process very inefficient); and 2) the radiation dose required for sufficient cross-linking also releases significant quantities of acetic acid—a by-product of the radiation exposure. Since the HDPE presents a barrier to gas transmission, the trapped acetic acid can render the fluid contents quite acidic—a very undesirable outcome.

U.S. Pat. No. 4,643,926 assigned to W. R. Grace discloses fabricating a medical solution container from a multilayered material where, in certain embodiments, the layer intended to be heat sealed is constructed with polypropylene as the main ingredient. Since it is well known that polypropylenes undergo chain scission when exposed to radiation, the heat seal layer remained thermoplastic and capable of being heat-sealed to similar surfaces. Therefore, the entire multilayer film can be heat-sealed and survive autoclaving. However, the complexity of the multilayer construction and the possible need of washing and incorporating acid scavenging compounds in the film (See U.S. Pat. No. 5,445,893) to remove the acidic by-products of irradiating EVA renders the process quite complicated and the cost very high. Further, since the film is constructed of several very dissimilar materials, process recycling of the edge trim and other film scraps is very difficult and impractical without greatly reducing the optical and mechanical properties.

U.S. Pat. No. 5,055,328 discloses a multilayer differentially cross-linked film where the heat-sealed layer contains additional antioxidants to retard cross-linking and to facilitate heat-sealing post cross-linking. Likewise, Canadian Patent 1,125,229 discloses another differential cross-linked multilayer film where the outer layer contains a cross-link enhancer. However, these constructions are all multilayer constructions and do not address the issue of self adhesion during autoclaving.

U.S. Pat. No. 4,724,176 to Sun discloses a multilayer, oriented, heat shrinkable container with a radiation cross-linked outer layer and, by controlling the irradiation process, a non cross-linked inner seal layer. The inner and outer layers can be of EVA copolymers. This container is designed to shrink upon application of heat, and, therefore, would be unsuitable for a container that must maintain substantially its entire volume after an autoclave process.

The main objective of the present invention is to provide polymeric materials that are, overall, superior to those materials, of which we are aware, which have been heretofore known in the art or have been commercially used or marketed. The properties of such materials include flexibility, optical transparency for visual inspection, and sufficient thermal resistance to withstand a steam sterilization process at temperatures up to 121° C. without experiencing significant distortion or self adhesion. The materials should also be non-oriented, non-adherent and capable of being sealed using heat sealing techniques. The materials should also be substantially free of low molecular weight leachable additives, and capable of safe disposal by incineration without the generation of significant amounts of corrosive inorganic acids. Finally, the material should serve as a cost-effective alternative to various PVC formulations currently being used for medical devices.

U.S. Pat. No. 5,879,768 discloses a pouch for packaging flowable materials fabricated from a material having a seal layer of a polymeric composition comprising: (A) 10 to 100 percent of a mixture of (1) from 5 to 95% of at least one homogeneously branched substantially linear ethylene/ α -

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olefin interpolymers, and (2) from 5 to 95% of high pressure low density polyethylene having a density from 0.916–0.930 g/cc; and (B) from 0–90% of one polymer selected from the group consisting of an ultra low density polyethylene, a linear low density polyethylene, a high pressure low density polyethylene, an ethylene vinyl acetate copolymer, and a homogeneously branched linear ethylene polymer. The '768 patent does not disclose exposing this blend to radiation nor does it disclose blending the homogeneously branched, substantially linear ethylene/ α -olefin interpolymers with polypropylene.

When more than one polymer is blended to form an alloying composition, it is difficult to achieve all of the above objectives simultaneously. For example, many alloys produce significant light scattering; thus, they fail to meet the optical clarity objective. The light scattering intensity (measured by haze) depends on the domain size of components in the micrometer (μ) range, and the proximity of the refractive indices of the components. As a general rule, the selection of components that can be satisfactorily processed into very small domain sizes, and yet with a minimum of refractive index mismatches, is a difficult task. The present invention is provided to solve these and other problems.

SUMMARY OF THE INVENTION

The present invention provides polymer blends for fabricating monolayer films or a layer within a multilayer film. The blend has a first and a second component. The first component is selected from the group of: (1) ethylene and α -olefin interpolymers having a density of less than about 0.915 g/cc, (2) ethylene and lower alkyl acrylate interpolymers, (3) ethylene and lower alkyl substituted alkyl acrylate interpolymers and (4) ionic polymers, commonly referred to as ionomers. The second component is selected from one or more of the following: (1) propylene containing polymers, (2) butene containing polymers, (3) polymethylpentene containing polymers, (4) cyclic olefin containing polymers and (5) bridged polycyclic hydrocarbon containing polymers. The first component is present in an amount from about 99% to about 55% and the second component is present in an amount by weight of about the blend from about 45% to about 1%.

The blend when fabricated into a film has a modulus of elasticity when measured in accordance with ASTM D882 of less than about 60,000 psi, an internal haze when measured in accordance with ASTM D1003 of less than about 25%, self adhesion ranking greater than about 2 as defined below, slight or no adhesion to overpouch materials, has a sample creep at 120° C. at about 27 psi loading of less than or equal to 150%, and the film can be heat sealed into a container having seals wherein the seals remain intact when a liquid filled container is autoclaved at 121° C. for one hour.

The present invention also provides a non-PVC, non-oriented, monolayer film having sufficient heat distortion resistance to withstand steam sterilization conditions. The film is fabricated from blend of a first and a second component. The first component is selected from the group of: (1) ethylene and α -olefin interpolymers having a density of less than about 0.915 g/cc, (2) ethylene and lower alkyl acrylate interpolymers, (3) ethylene and lower alkyl substituted alkyl acrylate interpolymers and (4) ionic polymers, commonly referred to as ionomers. The second component is selected from one or more of the following: (1) propylene containing polymers, (2) butene containing polymers, (3) polymethylpentene containing polymers, (4) cyclic olefin containing polymers and (5) bridged polycyclic hydrocar-

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bon containing polymers. The first component is present in an amount from about 99% to about 55% and the second component is present in an amount by weight of the blend from about 45% to about 1%.

The film has a modulus of elasticity when measured in accordance with ASTM D882 of less than about 60,000 psi, an internal haze when measured in accordance with ASTM D1003 of less than about 25%, self adhesion ranking greater than about 2 as defined below, slight or no adhesion to overpouch materials, has a sample creep at 120° C. at about 27 psi loading of less than or equal to 150%, and the film can be heat sealed into a container having seals wherein the seals remain intact when a liquid filled container is autoclaved at 121° C. for one hour.

The present invention further provides a method for fabricating a non-PVC and non oriented film. The method includes the steps of: providing a first and a second component, mixing the first component with the second component to define a blend, extruding the blend into a film and exposing the film to electron beam radiation. The first component is selected from the group of: (1) ethylene and α -olefin interpolymers having a density of less than about 0.915 g/cc, (2) ethylene and lower alkyl acrylate interpolymers, (3) ethylene and lower alkyl substituted alkyl acrylate interpolymers and (4) ionic polymers, commonly referred to as ionomers. The second component is selected from one or more of the following: (1) propylene containing polymers, (2) butene containing polymers, (3) polymethylpentene containing polymers, (4) cyclic olefin containing polymers and (5) bridged polycyclic hydrocarbon containing polymers. The first component is present in an amount from about 99% to about 55% and the second component is present in an amount by weight of the blend from about 45% to about 1%.

The film has a modulus of elasticity when measured in accordance with ASTM D882 of less than about 60,000 psi, an internal haze when measured in accordance with ASTM D1003 of less than about 25%, self adhesion ranking greater than about 2 as defined below, slight or no adhesion to overpouch materials, has a sample creep at 120° C. at about 27 psi loading of less than or equal to 150%, and the film can be heat sealed into a container having seals wherein the seals remain intact when a liquid filled container is autoclaved at 121° C. for one hour.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross-sectional view of a monolayer film of the present invention;

FIG. 2 is a cross-sectional view of a multiple layered film of the present invention;

FIG. 3 is a material container fabricated from a film of the present invention;

FIG. 4 is an I.V. fluid administration set;

FIG. 5 is a peritoneal dialysis container and tubing set; and

FIG. 6 is a dual chamber bag with a peelable seal separating the chambers.

DETAILED DESCRIPTION

The present invention is susceptible of embodiments in many different forms. Preferred embodiments of the invention are disclosed with the understanding that the present disclosure is to be considered as an exemplification of the principles of the invention and is not intended to limit the broad aspects of the invention to the embodiments illustrated.

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1. Polymer Blends and Monolayer Films Therefrom

FIG. 1 shows a monolayer film 10 of the present invention. The monolayer film 10 is fabricated from a polymer blend having a first component and a second component. The first component is selected from the group of: (1) ethylene and α -olefin interpolymers having a density of less than about 0.915 g/cc; (2) ethylene and lower alkyl acrylate interpolymers, (3) ethylene and lower alkyl substituted alkyl acrylate interpolymers and (4) ionic polymers, commonly referred to as ionomers. The first component is present in an amount from about 99% to about 55% by weight of the blend, more preferably from about 60%–85% and most preferably from about 65%–80%.

The second component is selected from the group consisting of: (1) propylene containing polymers, (2) butene containing polymers, (3) polymethyl pentene containing polymers, (4) cyclic olefin containing polymers and (5) bridged polycyclic hydrocarbon containing polymers. The second component is present in an amount by weight of the blend from about 45% to about 1%, more preferably from about 15%–40% and most preferably from about 20%–35%.

The film has a modulus of elasticity when measured in accordance with ASTM D882 of less than about 60,000 psi, an internal haze when measured in accordance with ASTM D1003 of less than about 25%, self adhesion ranking greater than about two (as defined below), slight or no adhesion to overpouch materials, has a sample creep at 120° C. at about 27 psi loading of less than or equal to 150%, and the film can be heat sealed into a container having seals wherein the seals remain intact when a liquid filled container is autoclaved at 121° C. for one hour.

As used herein, the term "interpolymer" includes copolymers, terpolymers either random or block.

Suitable ethylene and α -olefin interpolymers preferably have a density, as measured by ASTM D-792 of less than about 0.915 g/cc and are commonly referred to as very low density polyethylene (VLDPE), ultra low density ethylene (ULDPE) and the like. The α -olefin should have from 3–17 carbons, more preferably from 4–12 and most preferably 4–8 carbons. In a preferred form of the invention, the ethylene and α -olefin copolymers are obtained using single site catalysts. Suitable single site catalyst systems, among others, are those disclosed in U.S. Pat. Nos. 5,783,638 and 5,272,236. Suitable ethylene and α -olefin copolymers include those sold by Dow Chemical Company under the AFFINITY tradename, Dupont-Dow under the ENGAGE tradename and Exxon under the EXACT and PLASTOMER tradenames.

The term "lower alkyl acrylates" refers to comonomers having the formula set forth in Diagram 1:



Diagram 1

The R group refers to alkanes having from 1 to 17 carbons. Thus, the term "lower alkyl acrylates" includes but is not limited to methyl acrylate, ethyl acrylate, butyl acrylate and the like.

The term "alkyl substituted alkyl acrylates" refers to comonomers having the formula set forth in Diagram 2:



Diagram 2

R_1 and R_2 are alkanes having 1-17 carbons and can have the same number of carbons or have a different number of carbons. Thus, the term "alkyl substituted alkyl acrylates" includes but is not limited to methyl methacrylate, ethyl methacrylate, methyl ethacrylate, ethyl ethacrylate, butyl methacrylate, butyl ethacrylate and the like.

Suitable propylene containing polymers include those selected from the group consisting of homopolymers of propylene, copolymers and terpolymers of propylene with one or more comonomers selected from α -olefins having from 2-17 carbons. Suitable propylene copolymers and terpolymers include random or block propylene and ethylene copolymers or random or block propylene/ethylene/butene terpolymers. Suitable propylene and α -olefin copolymers are sold by Montell under the tradename PRO FAX, PRO FAX ULTRA and CATALLOY.

The present invention also contemplates using blends of propylene containing polymers as the second component of the blend. In a preferred form of the invention the blends include at least a first propylene containing polymer and a second propylene containing polymer. The first propylene containing polymer and the second propylene containing polymer can be selected from the propylene homopolymer, copolymers and terpolymers set forth above. In a preferred form of the invention the first propylene containing polymer differs from the second propylene containing polymer in at least one of two ways. The first difference is the first propylene containing polymer preferably should have a melt flow rate of from about 3 times greater and more preferably from about 5 times greater than the melt flow rate of the second propylene containing polymer. The second difference is the first propylene containing polymer preferably has a melting point from at least about 5° C. higher and more preferably from at least about 10° C. higher than that of the second propylene containing polymer. The melting point is measured in accordance with ASTM D3417 (Enthalpies of Fusion and Crystallization of Polymers by Differential Scanning Calorimetry). The first propylene containing polymer can differ from the second propylene containing polymer by the first difference, by the second difference or by both.

Suitable homopolymer and copolymers of cyclic olefins and bridged polycyclic hydrocarbons and blends thereof can be found in U.S. Pat. Nos. 5,218,049, 5,854,349, 5,863,986, 5,795,945, 5,792,824; and European Patent numbers EP 0 291,208, EP 0 283,164, EP 0 497,567 which are incorporated in their entirety herein by reference and made a part hereof.

In a preferred form of the invention, suitable cyclic olefin monomers are monocyclic compounds having from 5 to about 10 carbons in the ring. The cyclic olefins can be selected from the group consisting of substituted and unsubstituted cyclopentene, cyclopentadiene, cyclohexene, cyclohexadiene, cycloheptene, cycloheptadiene, cyclooctene, cyclooctadiene. Suitable substituents include lower alkyl, acrylate derivatives and the like.

In a preferred form of the invention, suitable bridged polycyclic hydrocarbon monomers have two or more rings and more preferably contain at least 7 carbons. The rings can be substituted or unsubstituted. Suitable substitutes include lower alkyl, aryl, aralkyl, vinyl, allyloxy, (meth)acryloxy and the like. The bridged polycyclic hydrocarbons are selected from the group consisting of those disclosed in the above incorporated patents and patent applications. Suitable bridged polycyclic hydrocarbon containing polymers are sold by Ticona under the tradename TOPAS, by Nippon Zeon under the tradename ZEONEX and ZEONOR, by Daikyo Gomu Seiko under the tradename CZ resin, and by Mitsui Petrochemical Company under the tradename APEL.

In a preferred form of the present invention the film will have the following physical characteristics: (1) a modulus of elasticity when measured in accordance with ASTM D882 of less than about 60,000 psi, (2) an internal haze when measured in accordance with ASTM D1003 of less than about 25%, (3) self adhesion ranking greater than about two as defined below, (4) no adhesion to overpouch materials, (5) has a sample creep at 120° C. at about 27 psi loading of less than or equal to 150%, and (6) the film can be heat sealed into a container having seals wherein the seals remain intact when a liquid-filled container is autoclaved at 121° C. for one hour.

The film is also sufficiently flexible to construct flowable material containers. The film has a modulus of elasticity of less than about 60,000 psi, more preferably less than about 40,000 psi, even more preferably less than about 30,000 and most preferably less than about 20,000 psi when measured in accordance with ASTM D-882. When the flowable material container is an I.V. container it is desirable the container collapse or substantially collapse upon draining, and, therefore, should have a modulus of elasticity of less than about 40,000 psi, more preferably less than about 30,000 psi, and even more preferably less than about 20,000 when measured in accordance with ASTM D-882.

For the purposes of this invention, self adhesion is defined as the tendency of the film to adhere to itself during autoclaving. This property can be determined with the following test. Film strips are cut 8"x2", with the larger dimension in the machine direction. These strips are rolled into 2" long tubes approximately 0.5" in diameter. The wound film is held in place by compressing the film layers together at one end with a paper clip. The tubes are then placed in a steam autoclave at 121° C. for 30 minutes. The samples are allowed to cool for at least one hour. The film is then unwound. The resistance to unwinding and relative damage to the film is ranked as shown in Table 1 as follows:

Table 1

Rank Observed Result

- 1 The film cannot be unwound without destroying the film.
- 2 The film is difficult to peel and significant surface damage results.
- 3 Some resistance to peeling and minor surface damage are noted.
- 4 Slight resistance to peeling noted with little or no surface damage.
- 5 No peel resistance and no surface damage noted.

Ranks are determined by three or more individuals and recorded as an average.

Adhesion to over pouch materials is determined by the following qualitative test. One inch wide strips of film are sealed into typical over pouch bags (medium or high density polyethylene). The over pouch bag is then placed into a

laboratory autoclave at 252° F. and 24.5 psig gauge pressure for one hour. After autoclaving, the bags are cut open and the strips removed. If the films separate from the over pouch without leaving damage marks on the film surface, a ranking of no adhesion (N) is given. If the film separation produces visible damage, a ranking is given (Y) indicating that tack to the over pouch is present. A ranking to indicate slight adhesion (S) can also be given.

Creep properties were determined at 120° C. by clamping film strips having a thickness from about 5 mils to about 15 mils in a temperature controlled oven and loading with weights to produce a stress of about 27 psi. After loading for 40 minutes, the film strips were removed and the dimensional changes in a pre-marked one inch gap were recorded.

The film is capable of being sealed using standard heat sealing techniques. An adequate heat seal is formed when a fluid container, such as the one shown in FIG. 3, is fabricated from the film by sealing peripheral edges to define a centrally disposed fluid chamber. The container is filled with water and subjected to a standard autoclave sterilization process. Adequate heat seals remain intact upon completion of the autoclave cycle.

The films of the present invention have a haze of less than about 25% and most preferably less than about 15% when measured in accordance with ASTM D1003. For the purposes of this invention, internal haze is defined as the haze value measured when both film surfaces have been wetted with isopropyl alcohol.

II. Polymer and Film Processing

To produce the film of the present invention, raw materials are fed into an extrusion hopper at the desired mix ratio employing weight feeders. The materials are extruded using an extrusion die to produce a mono-layer film. The film is irradiated with a suitable energy source and then sealed to form a fluid container. It is also contemplated exposing the blend to radiation before extrusion. The raw materials can also be pre-compounded before extrusion employing a single screw, twin screw or other compounding methods familiar to those skilled in the art.

The preferred method of irradiating the film is to expose it to an electron beam with beam energy from about 150 Kev-10 Mev, more preferably from 200-300 Kev and a dosage from about 20 kGys to about 200 kGys and more preferably from about 60-150 kGys. Alternatively, the film can be crosslinked using methods known to those skilled in the arts. Methods for crosslinking employed in the industry include exposure to ionizing radiation (gamma, beta, ultraviolet, etc.) and chemical (peroxides and condensing reactions).

To reduce or minimize the oxidative degradation of the film during and subsequent to electron beam exposure, it is desirable to reduce the partial pressure of oxygen in the area surrounding the film being exposed to the radiation. The oxygen partial pressure may be reduced by applying a vacuum or by applying another gas such as nitrogen under pressure or other known techniques for accomplishing this goal. In a preferred form of the invention the oxygen concentration during a nitrogen flush is less than about 100 ppm and more preferably less than about 40 ppm.

III. Multilayer Films

FIG. 2 shows an example of a multilayer film 20 including layer 12 of the mono-layer described above. In a preferred form of the invention the mono-layer shall be the seal layer. The multilayer film 20 can include any additional layer 14 or combination of additional layers selected from layers such as a skin layer, a radio frequency susceptible layer, a

water vapor barrier layer, a gaseous barrier layer, a scrap layer, a seal layer and a core layer to name a few.

The skin layer can be added to increase the scuff resistance of the film. The skin layer can be an olefin material such as homopolymers and copolymers of propylene and ethylene. The skin layer may also be a polyester, copolyester, polyamide or copolyamide. The term "copolyester" and the like is applied to polyesters synthesized from more than one diol and a dibasic acid. Copolyesters as used herein may also be characterized as copolymers of polyether and polyethylene terephthalate. More preferably copolyesters as used herein may be characterized as polymeric materials derived from 1,4 cyclohexane dimethanol, 1,4 cyclohexane dicarboxylic acid, and polytetramethylene glycol ether, or equivalents of any of the above, as reactants.

Suitable water vapor barriers include but are not limited to HDPE, MDPE and polyester (PET, PBT, PEN, etc.)

Suitable gaseous barriers are those that inhibit the passage of oxygen, carbon dioxide or other gases. Suitable gas barriers include but are not limited to polyesters and polyamides.

Scrap material generated prior to irradiation can be incorporated into one or more layers.

IV. Flowable Material Containers

FIG. 3 shows a flowable material container and particularly an I.V. container 30. FIG. 4 shows an I.V. administration set 40 and FIG. 5 shows a peritoneal dialysis set 50. The present invention further contemplates fabricating medical tubing from the blends of the present invention. It is contemplated that the radiation treatment of tubing will differ from films due to the increased thickness and round shape of tubing but tubing can be effectively treated within the radiation energy ranges set forth above for the film. What is meant by "flowable material" is a material that will flow by the force of gravity. Flowable materials therefore include both liquid items and powdered or granular items and the like. The container 30 has sidewalls 32 placed in registration and sealed along peripheral edges to define a chamber 34 for containing flowable materials such as fluids or granular material. For containers made through blow molding only or blow extrusion longitudinal edges would be sealed. A port tube 36 or multiple port tubes are provided to fill and empty the contents of the container 30. The sidewalls and port tube can be fabricated from one of the monolayer or multiple layered films set forth above. Surprisingly, the medical articles fabricated from the films and blends described above can be heat sealed even though the film has been irradiated with electron beam radiation.

Heat seals can be achieved using standard heat sealing techniques known to those skilled in the art.

V. Dual Chamber Peelable Seal Containers

FIG. 6 shows a dual chamber container 70 having a first chamber 72 and a second chamber 74 separated by a peelable seal 76. The container sidewalls 75 are fabricated from one of the polymer blends, monolayer films or multiple layered films set forth above. Dual chamber containers can be used for numerous applications such as separately housing two components for mixing later. The components can be liquid or powdered. The peelable seal can be created by modifying the sealing conditions such that the peelable seal 76 is capable of being ruptured by applying a force to a sidewall 75 of the container. Typically, one of the chambers will contain a liquid. By pressing on the container sidewall 75 over the liquid containing chamber the liquid contents will flow toward the peelable seal 76 and by applying sufficient pressure the seal 76 will rupture to allow mixing of the components stored in the separate chambers.

While FIG. 6 shows only one peelable seal 76, it is contemplated that numerous peelable seals could be provided to create numerous chambers. Further, FIG. 6 shows the peelable seal running between lateral edges. It is also contemplated that the peelable seals could extend between longitudinal edges or simply around an area not intersecting the permanent peripheral seam 79 to define a chamber.

The peelable seal 76 may be created simultaneously with sealing the peripheral sidewalls or before or after the creation of the permanent peripheral seals. The peelable seal 76 can be created by controlling sealing conditions. Peelable seals can be created with the application of lower temperature and pressure than employed to provide the permanent peripheral seal or by shortening the sealing times from that used to provide the permanent seal or the like. Further enhancement of the peel characteristics can be obtained with localized modification of the film surface characteristics (corona or other suitable treatment).

It is contemplated that the container can be sealed using ultrasonic welding techniques, conduction heat sealing techniques and other sealing techniques well known in the art.

VI. Examples

The blends identified in the table below were fabricated into a monolayer film using an extrusion process. The film was exposed to electron beam radiation having an acceleration voltage of from 200 Kev to 300 Kev for a dose set forth in the table that follows:

Dow Affinity PL 1880 is a ULDPPE having a density of 0.902 g/cc.

DuPont Dow Engage 8003 is a ULDPPE having a density of 0.885 g/cc.

Exxon PP305GE1 is a homopolymer of propylene (MFR 440).

Montell SA-861 is a propylene and ethylene copolymer (MFR 6.5).

Montell SA 982 is a propylene and ethylene copolymer (MFR 100).

"NA" means not available.

We claim:

1. A crosslinked non-diene containing polymer for fabricating monolayer films or a layer within a multilayer film, the polymer comprising:

a blend composed solely of a first component and a second component, the first component selected from the group consisting of: (1) ethylene and α -olefin copolymers having a density of less than about 0.915 g/cc, and (2) ionomers, the first component being present in an amount from about 99% to about 55% by weight of the blend;

the second component present in an amount by weight of the blend from about 45% to about 1% and selected from the group consisting of: (1) propylene containing polymers, (2) polybutene polymers, and (3) polymethylpentene polymers; and,

FORMULA	1	2	3	4	5	6	7	8	9	10
DuPont/Dow Engage 8003	100	95	90	80						70
Dow Affinity PL-1880					100	95	90	80	70	
Exxon PP305GE1		5	10	20						
Montell SA-861						5	10	20	30	20
Montell SG-982										10
Self adhesion rank —										
100 kGy	1	2	3.7	4	1	NA	1	2	4	NA
150 kGy	1	2	4.5	5	1	NA	1.3	2.3	3.3	NA
200 kGy	1	3.3	4.7	5	1	1.7	2	2	4	NA
Tack to over pouch —										
100 kGy	Y	S	N	N	Y	NA	Y	S	N	NA
150 kGy	Y	S	N	N	Y	NA	Y	N	N	NA
200 kGy	Y	S	N	N	Y	NA	Y	N	N	NA
120° C. Creep (%)										
0 kGy	NA	NA	NA	NA	NA	NA	Melts	NA	550	NA
100 kGy	200	138	88	41	263	NA	216	98	28	NA
150 kGy	63	38	31	18	43	NA	31	25	13	NA
200 kGy	25	13	16	16	21	22	16	9	22	NA
Autoclavability										
100 kGy	NA	NA	Y	Y	NA	NA	NA	Y	Y	Y
150 kGy	NA	NA	Y	Y	NA	NA	NA	Y	Y	Y
Internal Haze (ASTM D1003)	1	1.2	1.6	2.8	2.7	2.7	3.5	4.3	4.8	2.2
Tensile modulus (psi) (ASTM D882)	2860	3800	6650	16240	6110	NA	12830	19810	28820	21060

Dow Affinity PL 1880 is a ULDPPE having a density of 0.902 g/cc.

DuPont Dow Engage 8003 is a ULDPPE having a density of 0.885 g/cc.

Exxon PP305GE1 is a homopolymer of propylene (MFR 440).

Montell SA-861 is a propylene and ethylene copolymer (MFR 6.5).

Montell SA 982 is a propylene and ethylene copolymer (MFR 100).

"NA" means not available.

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the blend when fabricated into a film having a modulus of elasticity when measured in accordance with ASTM D882 of less than about 60,000 psi, an internal haze when measured in accordance with ASTM D1003 of less than about 25%, an internal adhesion ranking of greater than about 2, a sample creep at 120° C. under 27 psi loading of less than or equal to 150% for a film having a thickness of from about 5 mils to about 15 mils, and the film being capable of being heat sealed into a container having seals wherein the seals remain intact when the container is autoclaved at 121° C. for one hour.

2. The blend of claim 1 wherein the propylene containing polymer is selected from the group consisting of homopolymers of polypropylene, and random and block copolymers and random and block terpolymers of propylene with one or more comonomers selected from α -olefin having from about 2 to about 17 carbons.

3. The blend of claim 2 wherein the second component is a propylene and ethylene copolymer having an ethylene content of from 1–6% by weight of the copolymer.

4. The blend of claim 2 wherein the second component is a blend of a first propylene containing polymer and a second propylene containing polymer.

5. The blend of claim 4 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate wherein the first melt flow rate is about 3 times greater than the second melt flow rate.

6. The blend of claim 4 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate wherein the first melt flow rate is about 5 times greater than the second melt flow rate.

7. The blend of claim 4 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second melting point temperature wherein the first melting point temperature is higher than the second melting point temperature by at least about 5° C.

8. The blend of claim 4 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second melting point temperature wherein the first melting point temperature is higher than the second melting point temperature by at least about 10° C.

9. The blend of claim 1 wherein the α -olefin has from 3 to 17 carbons.

10. The blend of claim 1 wherein the α -olefin has from 4 to 8 carbons.

11. The blend of claim 10 wherein the ethylene and α -olefin copolymer is obtained using a single site catalyst.

12. The blend of claim 1 wherein the blend is subjected to electron beam radiation in a dosage amount from about 20 kGy to about 200 kGy.

13. The blend of claim 1 wherein the internal haze when measured in accordance with ASTM D1003 is less than 15%.

14. A crosslinked non-diene containing polymer for fabricating monolayer films or a layer within a multilayer film comprising:

a blend composed solely of a first component and a second component, the first component selected from the group consisting of: (1) ethylene and α -olefin copolymers having a density of less than about 0.915

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g/cc, and (2) ionomers, the first component being present in an amount from about 99% to about 55% by weight of the blend;

the second component present in an amount by weight of the blend from about 45% to about 1% and selected from the group consisting of: (1) propylene containing polymers, (2) polybutene polymers, and (3) polymethylpentene polymers; and,

wherein the blend is subjected to electron beam radiation in a dosage amount from about 20 kGy to about 200 kGy.

15. The blend of claim 14 wherein the blend when fabricated into a film having a modulus of elasticity when measured in accordance with ASTM D882 of less than about 60,000 psi, an internal haze when measured in accordance with ASTM D1003 of less than about 25%, an internal adhesion ranking of greater than about 2, a sample creep at 120° C. under 27 psi loading of less than or equal to 150% for a film having a thickness of from about 5 mils to about 15 mils, and the film being capable of being heat sealed into a container having seals wherein the seals remain intact when the container is autoclaved at 121° C. for one hour.

16. The blend of claim 14 wherein the blend is exposed to an oxygen partial pressure less than ambient conditions when exposed to the electron beam radiation.

17. The blend of claim 14 wherein the propylene containing polymer is selected from the group consisting of homopolymers of polypropylene, and random and block copolymers and random and block terpolymers of propylene with one or more comonomers selected from α -olefins having from about 2 to about 17 carbons.

18. The blend of claim 14 wherein the second component is a propylene and ethylene copolymer having an ethylene content of from 1–6% by weight of the copolymer.

19. The blend of claim 14 wherein the second component is a blend of a first propylene containing polymer and a second propylene containing polymer.

20. The blend of claim 19 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate wherein the first melt flow rate is about 3 times greater than the second melt flow rate.

21. The blend of claim 19 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate wherein the first melt flow rate is about 5 times greater than the second melt flow rate.

22. The blend of claim 19 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second melting point temperature wherein the first melting point temperature is higher than the second melting point temperature by at least about 5° C.

23. The blend of claim 19 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second melting point temperature wherein the first melting point temperature is higher than the second melting point temperature by at least about 10° C.

24. The blend of claim 14 wherein the α -olefin has from 3 to 17 carbons.

25. The blend of claim 14 wherein the α -olefin has from 4 to 8 carbons.

26. The blend of claim 24 wherein the ethylene and α -olefin copolymer is obtained using a single site catalyst.

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27. A crosslinked non-diene containing monolayer film comprising:

a blend composed solely of a first component and a second component, the first component selected from the group consisting of: (1) ethylene and α -olefin copolymers having a density of less than about 0.915 g/cc, and (2) ionomers, the first component being present in an amount from about 99% to about 55% by weight of the blend;

the second component present in an amount by weight of the blend from about 45% to about 1% and selected from the group consisting of: (1) propylene containing polymers, (2) polybutene polymers, and (3) polymethylpentene polymers; and,

the film has a modulus of elasticity when measured in accordance with ASTM D882 of less than about 60,000 psi, an internal haze when measured in accordance with ASTM D1003 of less than about 25%, an internal adhesion ranking of greater than about 2, a sample creep at 120° C. under 27 psi loading of less than or equal to 150% for a film having a thickness of from about 5 mils to about 15 mils, and the film being capable of being heat sealed into a container having seals wherein the seals remain intact when the container is autoclaved at 121° C. for one hour.

28. The film of claim 27 wherein the propylene containing polymer is selected from the group consisting of homopolymers of polypropylene, and random and block copolymers and random and block terpolymers of propylene with one or more comonomers selected from α -olefins having from about 2 to about 17 carbons.

29. The film of claim 28 wherein the second component is a propylene and ethylene copolymer having an ethylene content of from 1–6% by weight of the copolymer.

30. The film of claim 28 wherein the second component is a blend of a first propylene containing polymer and a second propylene containing polymer.

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31. The film of claim 30 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate wherein the first melt flow rate is about 3 times greater than the second melt flow rate.

32. The film of claim 30 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate wherein the first melt flow rate is about 5 times greater than the second melt flow rate.

33. The film of claim 30 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second melting point temperature wherein the first melting point temperature is higher than the second melting point temperature by at least about 5° C.

34. The film of claim 30 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second melting point temperature wherein the first melting point temperature is higher than the second melting point temperature by at least about 10° C.

35. The film of claim 27 wherein the α -olefin has from 3 to 17 carbons.

36. The film of claim 27 wherein the α -olefin has from 4 to 8 carbons.

37. The film of claim 36 wherein the ethylene and α -olefin copolymer is obtained using a single site catalyst.

38. The film of claim 27 wherein the blend is subjected to electron beam radiation in a dosage amount from about 20 kGy to about 200 kGy.

39. The film of claim 27 wherein the internal haze when measured in accordance with ASTM D 1003 is less than 15%.

40. A crosslinked non-diene containing monolayer film comprising:

a blend composed solely of a first component and a second component, the first component selected from the group consisting of: (1) ethylene and α -olefin copolymers having a density of less than about 0.915 g/cc, and (2) ionomers, the first component being present in an amount from about 99% to about 55% by weight of the film;

the second component present in an amount by weight of the film from about 45% to about 1% and selected from the group consisting of: (1) propylene containing polymers, (2) polybutene polymers, and (3) polymethylpentene polymers; and,

wherein the film is subjected to electron beam radiation in a dosage amount from about 20 kGy to about 200 kGy, and is capable of being heat sealed into a container having seals wherein the seals remain intact when the container is autoclaved at 121° C. for one hour.

41. The film of claim 40 has a modulus of elasticity when measured in accordance with ASTM D882 of less than about 60,000 psi, an internal haze when measured in accordance with ASTM D1003 of less than about 25%, an internal adhesion ranking of greater than about 2, a sample creep at 120° C. under 27 psi loading of less than or equal to 150% for a film having a thickness of from about 5 mils to about 15 mils, and the film being capable of being heat sealed into a container having seals wherein the seals remain intact when the container is autoclaved at 121° C. for one hour.

42. The film of claim 40 wherein the film is exposed to a oxygen partial pressure less than ambient conditions when exposed to the electron beam radiation.

43. The film of claim 40 wherein the propylene containing polymer is selected from the group consisting of homopolymers of polypropylene, and random and block copolymers and random and block terpolymers of propylene with one or more comonomers selected from α -olefins having from about 2 to about 17 carbons.

44. The film of claim 40 wherein the second component is a propylene and ethylene copolymer having an ethylene content of from 1-6% by weight of the copolymer.

45. The film of claim 40 wherein the second component is a blend of a first propylene containing polymer and a second propylene containing polymer.

46. The film of claim 45 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate wherein the first melt flow rate is about 3 times greater than the second melt flow rate.

47. The film of claim 45 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate wherein the first melt flow rate is about 5 times greater than the second melt flow rate.

48. The film of claim 45 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second melting point temperature wherein the first melting point temperature is higher than the second melting point temperature by at least about 5° C.

49. The film of claim 45 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second melting point temperature wherein the first melting point temperature is higher than the second melting point temperature by at least about 10° C.

50. The film of claim 40 wherein α -olefin has from 3 to 17 carbons.

51. The film of claim 40 wherein the α -olefin has from 4 to 8 carbons.

52. The film of claim 50 wherein the ethylene and α -olefin copolymer is obtained using a single site catalyst.

53. A method for preparing a non-oriented, non-diene and non-PVC containing film comprising the steps of:

providing a first component selected from the group consisting of: (1) ethylene and α -olefin copolymers having a density of less than about 0.915 g/cc, and (2) ionomers, the first component being present in an amount from about 99% to about 55% by weight of the blend;

providing a second component in an amount by weight of the blend from about 45% to about 1% and is selected from the group consisting of: (1) propylene containing polymers, (2) polybutene polymers, and (3) polymethylpentene polymers;

mixing the first component and the second component to define a blend;

crosslinking a portion of the blend; and

processing the blend into a monolayer film having a modulus of elasticity when measured in accordance with ASTM D882 of less than about 60,000 psi, an internal haze when measured in accordance with ASTM D 1003 of less than about 25%, an internal adhesion ranking of greater than about 2, a sample creep at 120° C. under 27 psi loading of less than or equal to 150% for a film having a thickness of from about 5 mils to about 15 mils, and the film being capable of being heat sealed into a container having seals wherein the seals remain intact when the container is autoclaved at 121° C. for one hour.

54. The method of claim 53 wherein the propylene containing polymer is selected from the group consisting of homopolymers of polypropylene, and random and block copolymers and random and block terpolymers of propylene with one or more comonomers selected from α -olefins having from about 2 to about 17 carbons.

55. The blend of claim 53 wherein the second component is a propylene and ethylene copolymer having an ethylene content of from 1-6% by weight of the copolymer.

56. The method of claim 53 wherein the second component is a blend of a first propylene containing polymer and a second propylene containing polymer.

57. The method of claim 53 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate wherein the first melt flow rate is about 3 times greater than the second melt flow rate.

58. The method of claim 56 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate wherein the first melt flow rate is about 5 times greater than the second melt flow rate.

59. The method of claim 56 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second melting point temperature wherein the first melting point temperature is higher than the second melting point temperature by at least about 5° C.

60. The method of claim 56 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second melting point temperature wherein the first melting point

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temperature is higher than the second melting point temperature by at least about 10° C.

61. The method of claim 53 wherein the α -olefin has from 3 to 17 carbons.

62. The method of claim 53 wherein the α -olefin has from 4 to 8 carbons.

63. The method of claim 62 wherein the ethylene and α -olefin copolymer is obtained using a single site catalyst.

64. The method of claim 53 wherein the crosslinking further comprises exposing the blend to electron beam radiation in a dosage amount from about 20 kGy to about 200 kGy.

65. The method of claim 53 wherein the step of processing the blend into a monolayer film comprises the step of extruding the blend.

66. A method for fabricating a non-diene monolayer film or a layer within a multilayer film comprising:

providing a first component selected from the group consisting of: (1) ethylene and α -olefin copolymers having a density of less than about 0.915 g/cc, and (2) ionomers, the first component being present in an amount from about 99% to about 55% by weight of the blend;

providing a second component in an amount by weight of the blend from about 45% to about 1% and is selected from the group consisting of: (1) propylene containing polymers, (2) polybutene polymers, and (3) polymethylpentene polymers;

mixing the first component with the second component to define a blend;

processing the blend into a monolayer film or a layer within a multiple layered film to define a structure; and, crosslinking the structure with electron beam radiation in a dosage amount from about 20 kGy to about 200 kGy.

67. The method of claim 66 wherein the film has a modulus of elasticity when measured in accordance with ASTM D882 of less than about 60,000 psi, an internal haze when measured in accordance with ASTM D1003 of less than about 25%, an internal adhesion ranking of greater than about 2, a sample creep at 120° C. under 27 psi loading of less than or equal to 150% for a film having a thickness of from about 5 mils to about 15 mils, and the film being capable of being heat sealed into a container having seals wherein the seals remain intact when the container is autoclaved at 121° C. for one hour.

68. The method of claim 66 wherein the crosslinking includes the step of reducing an oxygen partial pressure to less than ambient conditions.

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69. The method of claim 66 wherein the propylene containing polymer is selected from the group consisting of homopolymers of polypropylene, and random and block copolymers and random and block terpolymers of propylene with one or more comonomers selected from α -olefins having from about 2 to about 17 carbons.

70. The method of claim 66 wherein the second component is a propylene and ethylene copolymer having an ethylene content of from 1-6% by weight of the copolymer.

71. The method of claim 66 wherein the second component is a blend of a first propylene containing polymer and a second propylene containing polymer.

72. The method of claim 71 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate wherein the first melt flow rate is about 3 times greater than the second melt flow rate.

73. The method of claim 71 wherein the first propylene containing polymer has a first melt flow rate and the second propylene containing polymer has a second melt flow rate wherein the first melt flow rate is about 5 times greater than the second melt flow rate.

74. The method of claim 71 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second melting point temperature wherein the first melting point temperature is higher than the second melting point temperature by at least about 5° C.

75. The method of claim 71 wherein the first propylene containing polymer has a first melting point temperature and the second propylene containing polymer has a second melting point temperature wherein the first melting point temperature is higher than the second melting point temperature by at least about 10° C.

76. The method of claim 66 wherein the α -olefin has from 3 to 17 carbons.

77. The method of claim 66 wherein the α -olefin has from 4 to 8 carbons.

78. The method of claim 77 wherein the ethylene and α -olefin copolymer is obtained using a single site catalyst.

79. The method of claim 66 wherein the step of processing the blend includes the step of extruding the blend into a film or a layer within a multiple layered film.

* * * * *

EXHIBIT F



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,136	07/27/2001	Sherwin Shang	DI-5596A	3282
29200	7590	08/23/2006		
BAXTER HEALTHCARE CORPORATION 1 BAXTER PARKWAY DF2-2E DEERFIELD, IL 60015				
EXAMINER MULLIS, JEFFREY C				
ART UNIT		PAPER NUMBER		
1711				

DATE MAILED: 08/22/2006

Date Due: 9/11/22/06

Please find below and/or attached an Office communication concerning this application or proceeding.

RECEIVED

AUG 1 2006

Corporate Patent Administration

Office Action Summary**Application No.**

09/917,136

Applicant(s)

SHANG ET AL.

Examiner

Jeffrey C. Mullis

Art Unit

1711

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-19 and 145-161 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-19 and 145-161 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Claims 16-19 and 145-161 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as filed does not disclose that the second component is "free of cross-linking" but merely discloses "essentially free" of crosslinking and gives no indication that all traces of crosslinking can be eliminated from the second component and this limitation is therefore new matter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16-19 and 145-161 are rejected under 35 U.S.C. 102(e) as being anticipated or in the alternative obvious by Woo et al. (US 6,743,523)

The instant claim recite that the second component "free of crosslinking", a disclosure not supported by the parent and the effective filing date of the instant case is the actual filing date, 7-27-01. The term "free" in fact appears only twice in the parent case specification and in neither instance pertains to crosslinking. Additionally the

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dependent claims recite use of 4-methylpentene-1 (at least claim 16) and 75% first component (at least claim 19), features not present in the parent case.

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Woo et al. in the examples 2-10 at column 10, lines 46 et seq disclose a "monolayer" film crosslinked by electron beam radiation having applicants amounts of polypropylene (PP3505GE1) and polyethylenes such as Engage 8003 or Affinity PL-1880.

It is noted that applicants are claiming a monolayer film not a multilayer film and therefore the application and patent claims are not obvious variations. Applicants examples and patentees are identical and hence reasonably appear to share and characteristics.

When the reference discloses all the limitations of a claim except a property or function, and the Examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention, basis

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exists for shifting the burden of proof to applicant. Note In re Fitzgerald et al. 619 F. 2d 67, 70, 205 USPQ 594, 596, (CCPA 1980). See MPEP § 2112-2112.02.

Applicant's arguments filed 6-12-06 have been fully considered but they are not persuasive. The filing date of the instant claims is 7-27-2001 since a single embodiment is not sufficient to support the full scope of the claims which recite various genres and ranges, On the other hand a single embodiment reading on a claim is sufficient to meet the requirements of anticipation.

Any inquiry concerning this communication should be directed to Jeffrey C. Mullis
M-F, 9-5 PM at telephone number 571 272 1075.

Jeffrey C. Mullis
J Mullis
Art Unit 1711

JCM

8-17-06

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16-19 and 145-161 are rejected under 35 U.S.C. 102(e) as being anticipated by Woo et al. (US 6,743,523)

The instant claim recite an upper limit of 95% of first component which is broadly an ethylene containing polymer and lower level of 5% second component, a disclosure not supported by the parent and the effective filing date of the instant case is the actual filing date, 7-27-01.

The applied reference has a common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Woo et al. in the examples 2-10 at column 10, lines 46 et seq disclose a "monolayer" film crosslinked by electron beam radiation having applicants amounts of polypropylene (PP3505GE1) and polyethylenes such as Engage 8003 or Affinity PL-1880.

It is noted that applicants are claiming a monolayer film not a multilayer film and therefore the application and patent claims are not obvious variations.

Braga, (US 6,204,330), previously cited of interest discloses a crosslinked polyolefin composition requiring numerous polyolefin components. Since applicants films comprise

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solely a first component and second component (ie two components) the reference does not anticipate or render the claims obvious.

The terminal disclaimer filed on 12-12-06 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US patent 6,969,483 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Applicant's arguments filed 12-12-05 have been fully considered but they are not persuasive. The term "essentially free" does not appear in the parent case and the effective filing date of the instant case is therefore that of the actual filing date, 7-12-01.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication should be directed to Jeffrey C. Mullis
at telephone number 571 272 1075.

Jeffrey C. Mullis
J Mullis
Art Unit 1711

JCM

3-3-06

JEFFREY C. MULLIS
PRIMARY EXAMINER
GROUP 1200

